

Nancy M. Erfle, OSB No. 902570  
[nerfle@grsm.com](mailto:nerfle@grsm.com)  
GORDON REES SCULLY MANSUKHANI, LLP  
1300 SW Fifth Avenue, Suite 2000  
Portland, OR 97201  
Telephone: (503) 382-3852  
Facsimile: (503) 616-3600

Taylor T. Daly (admitted *pro hac vice*)  
[Taylor.daly@nelsonmullins.com](mailto:Taylor.daly@nelsonmullins.com)  
Brandee J. Kowalzyk (admitted *pro hac vice*)  
[Brandee.kowalzyk@nelsonmullins.com](mailto:Brandee.kowalzyk@nelsonmullins.com)  
Richard B. North, Jr. (admitted *pro hac vice*)  
[Richard.north@nelsonmullins.com](mailto:Richard.north@nelsonmullins.com)  
Shaniqua L. Singleton (admitted *pro hac vice*)  
[Shaniqua.singleton@nelsonmullins.com](mailto:Shaniqua.singleton@nelsonmullins.com)  
Philip M. Busman (admitted *Pro Hac Vice*)  
[Phil.busman@nelsonmullins.com](mailto:Phil.busman@nelsonmullins.com)  
James F. Rogers (admitted *pro hac vice*)  
[jim.rogers@nelsonmullins.com](mailto:jim.rogers@nelsonmullins.com)  
Elizabeth C. Helm (admitted *pro hac vice*)  
[kate.helm@nelsonmullins.com](mailto:kate.helm@nelsonmullins.com)  
Mark R. Nash, admitted *Pro Hac Vice*  
[Mark.nash@nelsonmullins.com](mailto:Mark.nash@nelsonmullins.com)  
NELSON MULLINS RILEY & SCARBOROUGH LLP  
201 17<sup>th</sup> Street NW, Suite 1700  
Atlanta, GA 30363  
Telephone: (404) 322-6000  
Facsimile: (404) 322-6050

*Attorneys for Defendants C. R. Bard, Inc.  
and Bard Peripheral Vascular, Inc.*

IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF OREGON

JUSTIN PETERSON,

Plaintiff,

vs.

C. R. BARD INC. and BARD PERIPHERAL  
VASCULAR, INC.,

Defendants.

Case No. 3:19-cv-01701-MO

**DEFENDANTS' RESPONSE IN  
OPPOSITION TO PLAINTIFF'S  
MOTION IN LIMINE AND  
MEMORANDUM IN SUPPORT**

DEFENDANTS' RESPONSE IN OPPOSITION TO  
PLAINTIFF'S MOTION IN LIMINE AND  
MEMORANDUM IN SUPPORT

**GORDON REES SCULLY MANSUKHANI, LLP**  
1300 SW Fifth Avenue, Suite 2000  
Portland, OR 97201  
Telephone: (503) 382-3852  
Facsimile: (503) 616-3600

## **TABLE OF CONTENTS**

TABLE OF AUTHORITIES .....	iv
1. Any reference to IVC filter litigation as “lawyer driven litigation” or any similar description.....	1
2. Anecdotal testimony .....	2
3. Evidence of good character or acts .....	3
4. Any references to Plaintiff’s prior arrest for DUI .....	4
5. References to any other Bard non-filter products.....	4
6. Irrelevant references to experts.....	5
A. References to experts not called to testify in this case .....	5
B. References to the number of times an expert has testified in other case [sic] against manufacturers other than Bard.....	6
7. Irrelevant/misleading references re: alleged complaint/failure rates and re: the medical community .....	7
A. Bard’s reported complication rates are highly relevant evidence.....	8
B. Bard’s sales figures are relevant and should not be excluded .....	9
C. Bard does not intend to suggest any specific percentage of doctors use IVC filters...	9
D. Evidence of the medical community’s knowledge is relevant .....	10
8. Evidence of trade associations or organizations’ opinions for the purpose of supporting legal theories or acceptable rates of complications and safety profiles.....	10
A. Such material is highly relevant to Plaintiff’s claims.....	10
B. Such material is admissible as non-hearsay, an exception to hearsay, and as a basis of opinions offered by Bard’s medical experts .....	11
C. The probative value substantially outweighs any danger of prejudice.....	13
D. Plaintiff misconstrues Dr. Grassi’s testimony .....	14

9. Any reference to the number of documents that defendants have produced or the number of current and/or former employees that defendants have produced for depositions .....	15
10. Any suggestion that Plaintiff was told he needed or should have his filter retrieved from any medical doctor or office or other person prior to Feb. 14, 2015.....	16
A. The record evidence clearly indicates that Dr. Goodman chose the Eclipse because he valued the option to retrieve, and was hopeful Plaintiff’s Filter could be retrieved .....	16
11. Any suggestion that Plaintiff’s filter caught or stopped a clot and saved his life .....	17
12. Any reference to any family history of blood clots and deep vein thrombosis .....	18
13. Any reference to Mr. Peterson’s use of substances .....	19
13. Any reference to Mr. Peterson’s consumption of alcohol as the cause of his hypercoagulable state .....	20
14. References to or assertion of the “Empty Chair” defense .....	20
15. Any reference to or evidence of a collateral source having paid any of Mr. Peterson’s expenses or damage related to the injuries at issue .....	21
16. Reference that Bard was precluded from sending warning letters, changing the instructions for use to add or strengthen a warning regarding the risks of migration, perforation, and/or death associated with its IVC filters, or effectuating a removal/recall without the consent of the FDA .....	22
A. Bard cannot include in its labeling comparative rate information or increased risks warnings based solely on MDR or MAUDE Data, and Plaintiff has proffered no purported “other reliable sources” to support his proposed warnings .....	22
B. Bard does not intend to suggest that it was precluded from sending warning letters to physicians .....	24
C. Bard does not dispute that a manufacturer may voluntarily initiate a recall but there is an important role for FDA in the recall process.....	25
17. Argument and evidence regarding the Surgeon General’s 2008 call to action .....	26
A. The Surgeon General’s Call to Action is admissible under the public records hearsay exception.....	27

B. The Surgeon General’s Call to Action is relevant, not prejudicial, and will not mislead the jury.....	28
18. References to that clearance of Bard IVC filters by the FDA and/or lack of FDA enforcement action regarding same constitutes proof of safety and/or efficacy .....	31
A. Factual Background.....	32
B. FDA’s clearance of the Filter is relevant under Pennsylvania law.....	35
C. FDA’s clearance of the Filter is relevant because safety and efficacy play an important role in 510(k) review .....	38
D. <i>Lohr</i> addressed preemption – not evidentiary standards .....	38
E. FDA’s lack of enforcement action regarding the Filter is relevant .....	39
F. FDA’s clearance of the Filter and lack of enforcement action is not unfairly prejudicial .....	40
G. FDA’s clearance and lack of enforcement action will not result in a mini-trial.....	42
19. Any reference to IVC filters as lifesaving devices or to statistics of thrombi and pulmonary emboli .....	43
A. There is abundant evidence showing that Bard’s IVC Filters can be lifesaving .....	44
B. Evidence that Bard’s Eclipse Filter has a clinical benefit and can be a “lifesaving” device and statistics related to pulmonary emboli are relevant .....	46
C. Judge Campbell in Bard’s IVC Filter MDL denied a similar motion in limine trying to exclude evidence that filters are lifesaving devices, and recently the Eastern District of Pennsylvania (applying Pennsylvania law) did the same.....	48
D. The medical literature cited by Plaintiff does not show that Bard’s IVC Filters have no clinical benefit or that they are not lifesaving devices .....	49
E. Relevant evidence related to the purpose of Bard’s IVC Filters should not be excluded pursuant to Rule 403 .....	49
CONCLUSION.....	49
CERTIFICATE OF COMPLIANCE.....	51

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>Baker v. Adventist Health, Inc.</i> , 260 F.3d 987 (9th Cir. 2001) .....	29
<i>In re: Bard IVC Filters Prod. Liab. Litig.</i> , No. CV-16-00782-PHX-DGC, 2018 WL 1993767 (D. Ariz. Apr. 27, 2018) .....	24
<i>In re Bard IVC Filters Prod. Liab. Litig.</i> , No. MDL 15-02641-PHX DGC, 2017 WL 5625547 (D. Ariz. Nov. 22, 2017), <i>aff'd</i> , 969 F.3d 1067 (9th Cir. 2020) .....	32, 38
<i>In re Bard IVC Filters Prod. Liab. Litig.</i> , No. CV-16-00474-PHX-DGC, 2018 WL 1109554 (D. Ariz. Mar. 1, 2018) .....	<i>passim</i>
<i>In re Bard IVC Filters Prod. Liab. Litig.</i> , No. CV-16-00474-PHX-DGC, 2018 WL 934795 (D. Ariz. Feb. 15, 2018) .....	4
<i>In re Bard IVC Filters Prod. Liab. Litig.</i> , No. CV-16-00782-PHX-DGC, 2018 WL 2095829 (D. Ariz. May 3, 2018) .....	1, 6
<i>In re Bard IVC Filters Prod. Liab. Litig.</i> , No. CV-16-00893-PHX-DGC, 2018 WL 4215028 (D. Ariz. Sept. 4, 2018) .....	11, 13
<i>In re Bard IVC Filters Prod. Liab. Litig.</i> , No. CV-16-00893-PHX-DGC, 2018 WL 4279833 (D. Ariz. Sept. 7, 2018) .....	27, 29, 40
<i>In re Bard IVC Filters Prods. Liab. Litig.</i> , 289 F. Supp. 3d 1045 (D. Ariz. 2018) .....	<i>passim</i>
<i>Birt v. Firstenergy Corp.</i> , 891 A.2d 1281 (Pa. Super. 2006) .....	36
<i>Block v. Woo Young Medical Co. Ltd.</i> , 937 F. Supp. 2d 1028 (D. Minn. 2013) .....	37
<i>Buttice v. G.D. Searle &amp; Co.</i> , 938 F. Supp. 561 (E.D. Mo. 1996) .....	12
<i>Campos v. MTD Prod., Inc.</i> , No. 2:07-0029, 2009 WL 920337 (M.D. Tenn. Apr. 1, 2009) .....	7

<i>Chalk v. U.S. Dist. Ct. Cent. Dist. of California</i> , 840 F.2d 701 (9th Cir. 1988) .....	30
<i>Coney v. NPR, Inc.</i> , No. CIV A 03-1324, 2006 WL 2601507 (E.D. Pa. Sept. 11, 2006) .....	21
<i>In re Cook Med., Inc., IVC Filters Mktg., Sales Practices &amp; Prod. Liab. Litig.</i> , 114ML02570RLYTAB, 2018 WL 6617375 (S.D. Ind. Dec. 18, 2018) .....	37
<i>Goldberg v. Boone</i> , 912 A.2d 698 (Md. Ct. App. 2006) .....	7
<i>Gruca v. Alpha Therapeutic Corp.</i> , 51 F.3d 638 (7th Cir. 1995) .....	28
<i>Hibu, Inc. v. Peck</i> , No. 16-1055-JTM, 2018 WL 372437 (D. Kan. Jan. 11, 2018) .....	5
<i>Hrymoc v. Ethicon, Inc.</i> , No. A-1083-18, 2021 WL 787039 (N.J. Super. Ct. App. Div. Mar. 2, 2021) .....	38, 41
<i>Jacobs v. Leblanc</i> , 639 F. App'x 252 (5th Cir. 2016) .....	27
<i>Jacobs v. LeBlanc</i> , No. 3:10-CV-00271-JWD, 2015 WL 364170 (M.D. La. Jan. 26, 2015), <i>aff'd</i> , 639 F. App'x 252 (5th Cir. 2016) .....	27
<i>Kaiser v. Johnson &amp; Johnson</i> , 947 F.3d 996 (7th Cir. 2020) .....	37
<i>Keen v. C. R. Bard, Inc.</i> , 480 F. Supp. 3d 646 (E.D. Pa. 2020) .....	<i>passim</i>
<i>Kennedy v. Sell</i> , 816 A.2d 1153 (Pa. Super. Ct. 2003) .....	21
<i>Kline v. Zimmer Holdings, Inc.</i> , 662 F. App'x 121 (3d Cir. 2016) .....	3
<i>Lance v. Wyeth</i> , 85 A.3d 434 (Pa. 2014) .....	30, 36
<i>Ledezma-Cosino v. Sessions</i> , 857 F.3d 1042 (9th Cir. 2017) .....	29

<i>In re M &amp; L Bus. Mach. Co., Inc.</i> , 198 B.R. 800 (D. Colo. 1996) .....	15
<i>McHenry v. PacificSource Health Plans</i> , 679 F. Supp. 2d 1226 (D. Or. 2010) .....	29
<i>Medtronic, Inc. v. Lohr</i> , 518 U.S. 470 (1996) .....	38
<i>Metzgar v. Playskool Inc.</i> , 30 F.3d 459 (3d Cir. 1994) .....	3
<i>Moorhead v. Crozer Chester Med. Ctr.</i> , 765 A.2d 786 (Pa. 2001), <i>overruled on other grounds</i> , <i>Northbrook Life Ins.</i> <i>Co. v. Com.</i> , 949 A.2d 333 (Pa. 2008) .....	22
<i>Musgrave v. Breg, Inc.</i> , No. 2:09-CV-01029, 2011 WL 4620767 (S.D. Ohio Oct. 3, 2011) .....	37
<i>Philip Morris USA, Inc. v. Pollari</i> , 228 So. 3d 115 (Fla. 4th DCA 2017) .....	27, 28
<i>Pritchett v. I-Flow Corp.</i> , No. 09-CV-02433-WJM-KLM, 2012 WL 1340384 (D. Colo. Apr. 18, 2012) .....	37
<i>Shaheen v. Advantage Moving &amp; Storage, Inc.</i> , 860 N.E.2d 375 (Ill. App. Ct. 2006) .....	7
<i>Soliman v. Philip Morris Inc.</i> , 311 F.3d 966 (9th Cir. 2002) .....	29
<i>In re: Tylenol (Acetaminophen) Mktg.</i> , No. 2436, 2016 WL 3125428 (E.D. Pa. June 3, 2016) .....	3, 5
<i>United States v. Abel</i> , 469 U.S. 45 (1984) .....	6
<i>United States v. Harris</i> , 185 F.3d 999 (9th Cir. 1999) .....	7
<b>Statutes</b>	
42 Pa. Cons. Stat. Ann. § 7102 .....	20

## Rules

21 C.F.R. § 7.46 .....	25
21 C.F.R. § 820.198(a).....	9
21 C.F.R. § 870.3775 .....	33, 35
Fed. R. Evid. 401, 402 .....	4, 6
Fed. R. Evid. 403 .....	13
Fed. R. Evid. 705 .....	15
Fed. R. Evid. 801(c)(2) .....	12, 30
Fed. R. Evid. 803(18)(A) & (B).....	13

## Other Authorities

3 West’s Pa. Prac., Torts: Law and Advocacy § 9.34 (Dec. 2020).....	3
45 Fed. Reg. 17736 (FDA Feb. 5, 1980) .....	32
65 Fed. Reg. 17138 (FDA Mar. 31, 2000).....	33
65 Fed. Reg. 17144 (FDA Mar. 31, 2000).....	33
David F. Binder, Hearsay Handbook § 1:9 (4th ed. 2015) .....	12
PBI, <i>Pennsylvania Suggested Standard Civil Jury Instructions</i> (4th ed. 2018 supp.).....	30
Surgeon General’s Calls to Action, available at <a href="https://www.surgeongeneral.gov/library/calls/index.html">https://www.surgeongeneral.gov/library/calls/index.html</a> (last visited Apr. 1, 2021) .....	28

**1. Any reference to IVC filter litigation as “lawyer driven litigation” or any similar description.**

Bard objects to this Motion to the extent Plaintiff seeks to restrict Bard’s ability to introduce evidence regarding attorney advertising necessary to place Plaintiff’s expected evidence in its proper context. For example, Plaintiff’s deposition designations in this case indicate that he intends to introduce testimony and evidence regarding an internal Bard document for the Eclipse Filter that states: “The change in brand name and codes was to create a break with the baggage associated with the previous versions despite the fact that the new iteration was the same as G2X in every way but one.” (*See, e.g.*, Declaration of James F. Rogers in Support of Defendants’ Response in Opposition to Plaintiff’s Omnibus Motion *in Limine* (“Rogers Decl.”), Ex. 1, July 27, 2016 Bill Little Dep. at 208:16-20; Doc. 108-1, at 81 (designating pages 205:16–209:2 of Mr. Little’s deposition).) But the “baggage” referred to in that email specifically was “the filter law website”—filterlaw.com—an attorney advertising website sponsored by two law firms intended to recruit plaintiffs to “join” the litigation.<sup>1</sup> (*Id.* at 205:3-25, 209:8-14.) Thus, because putting Plaintiff’s expected evidence into proper context requires referencing attorney advertising, Bard respectfully requests that the Court leave the door open for Bard to introduce it at trial, if necessary.<sup>2</sup>

Bard also opposes this Motion to the extent Plaintiff seeks to prevent Bard from following up with jurors, if the Court permits, during oral *voir dire*, particularly if a response to the juror

<sup>1</sup>*See* <https://web.archive.org/web/20130107082243/http://www.filterlaw.com:80/Practice-Areas/Status-of-Litigation.shtml> (last accessed April 11, 2021).

<sup>2</sup> In the MDL, when presented with a similar motion, the court deferred ruling until trial on whether Bard was prohibited from introducing evidence of attorney advertising in this scenario, holding that if plaintiffs introduced the “break with baggage” evidence, Bard would be permitted to raise the issue outside the presence of the jury. *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00782-PHX-DGC, 2018 WL 2095829, at \*6 (D. Ariz. May 3, 2018).

questionnaire mentions attorney advertising. A potential juror’s exposure to attorney advertising about the IVC filter litigation—which has been aggressive and widespread—is a possible source of bias against Bard. While Plaintiff’s counsel’s desire to distance themselves from attorney advertising is understandable, Bard’s need to determine whether potential jurors are biased due to such extensive, hyperbolic, and often incorrect advertising substantially outweighs any prejudice such questions could create.

## 2. Anecdotal testimony.

Multiple federal courts have rejected attempts by plaintiffs to exclude references to IVC filters as “lifesaving” devices. In the MDL, Judge Campbell denied a motion where the plaintiffs sought to preclude Bard from describing its filters as lifesaving or “life-extending.” Judge Campbell reasoned that evidence of the benefits of IVC filters was relevant to the risk-utility analysis for design defect claims: “*Evidence concerning the benefits of IVC filters is directly relevant [to a risk-utility analysis].* Plaintiffs’ motion in limine is denied.” *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00474-PHX-DGC, 2018 WL 1109554, at \*\*4-5 (D. Ariz. Mar. 1, 2018) (emphasis added).

More recently, in *Keen v. C. R. Bard, Inc.*, 480 F. Supp. 3d 646 (E.D. Pa. 2020), Judge Pratter denied a nearly identical motion. He emphasized that evidence of an IVC filter’s ability to save lives is relevant to the “risks and benefits” of the filter and necessary to provide the jury context about why the plaintiff received the device:

*Without understanding both the risks and benefits of the filter, the jury would be left without the proper context to understand why Bard would ever design or manufacture IVC filters or why Dr. Sacks implanted the G2X filter in Mr. Keen. The purpose of Bard’s IVC filters and their medical benefits are also relevant to the inquiry of whether Bard violated its duty of care when designing the G2X filter.*

*Id.* at 652 (emphasis added). Similarly here, evidence of the number of citizens who die from PE, and testimony regarding the benefits of IVC filters, is directly relevant (a) to the risk-benefit analysis applicable under Pennsylvania law, and (b) to explain why Dr. Jay Goodman chose to treat Mr. Peterson with the Eclipse filter. *See, e.g., id.* (applying Pennsylvania law) (finding “risks and benefits” relevant to negligent design and failure to warn claims involving Bard IVC filter); *Metzgar v. Playskool Inc.*, 30 F.3d 459, 462 (3d Cir. 1994) (citations omitted) (applying Pennsylvania law) (“With regard to the negligence claim, the district court properly engaged in a risk-utility analysis.”); *accord Kline v. Zimmer Holdings, Inc.*, 662 F. App’x 121, 124–26 (3d Cir. 2016) (citations omitted) (applying Pennsylvania law) (affirming summary judgment on negligent design claim in medical device case where the plaintiff “failed to produce record evidence showing any of these design choices were unreasonable,” meaning “evidence from which a jury could find that the allegedly faulty design changes increased risk more than they increased utility.”).<sup>3</sup>

### **3. Evidence of good character or acts.**

This Court should deny Plaintiff’s Motion regarding evidence of good character for two primary reasons. **First**, it is impermissibly vague and overly broad, seeking to exclude extensive, nebulous categories of evidence rather than specific items. *See In re: Tylenol (Acetaminophen) Mktg.*, No. 2436, 2016 WL 3125428, \*9 (E.D. Pa. June 3, 2016) (denying motion to exclude

---

<sup>3</sup> *See generally* 3 West’s Pa. Prac., Torts: Law and Advocacy § 9.34 (Dec. 2020) (citations omitted) (“In addition to foreseeability of the risk, for a product supplier to be held liable for negligence, the risk to the plaintiff must be unreasonable. In determining the reasonableness of a risk, the courts essentially engage in a form of risk utility analysis, balancing the risks of the product against the social value of the interests that it threatens, the probability and extent of any harm, and the defendant’s ability to guard against the risk.”).

evidence of defendants' reputation and good acts as vague and unclear).<sup>4</sup> **Second**, the evidence Plaintiff seeks to exclude is the type of identifying background information that is "universally" admitted as helpful to the jury's understanding of the parties and the case, and Bard would be unfairly prejudiced if it were not allowed to present evidence of its corporate identity. Fed. R. Evid. 401, advisory committee's note (1972) ("Evidence which is essentially background in nature . . . is universally offered and admitted as an aid to understanding."). In denying a near identical motion filed in the MDL, the court found that "some evidence regarding the nature of Defendants' business is relevant to the jury's understanding of the issues in this case" and "Defendants must be permitted to rebut Plaintiffs' themes . . . that Defendants knowingly disregarded patient safety, used patients for experimentation, and placed profits over safety." *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00474-PHX-DGC, 2018 WL 934795, at \*2 (D. Ariz. Feb. 15, 2018).

**4. Any references to Plaintiff's prior arrest for DUI.**

Bard does not intend to affirmatively introduce evidence of Plaintiff's DUI arrest but reserves the right to raise it during cross examination if Plaintiff opens the door or otherwise causes it to become relevant.

**5. References to any other Bard non-filter products.**

Plaintiff's Motion impermissibly seeks to exclude evidence that will be necessary to help the jury understand Bard's corporate identity and to combat Plaintiff's anticipated attacks on Bard's employees. *See* Fed. R. Evid. 401, 402. "[S]ome evidence regarding the nature of [Bard's] business is relevant to the jury's understanding of the issues in this case." *Id.*; *see also In re:*

---

<sup>4</sup> Since Plaintiff has not articulated with specificity the evidence he seeks to exclude, should the Court not deny the Motion outright, Bard requests that the admissibility of evidence that might fall within the vast ambit of the Motion be addressed at trial on a case-by-case basis.

*Tylenol*, 2016 WL 3125428 at \*11; *Hibu, Inc. v. Peck*, No. 16-1055-JTM, 2018 WL 372437, at \*3 (D. Kan. Jan. 11, 2018) (“[To] the extent [a party’s] corporate history . . . provides helpful background information to the jury, such evidence is admissible.”).

In addition, Bard expects that Plaintiff will push a “greedy salesman” narrative, and Bard must be able to present evidence like it did in the MDL that will help the jury understand the scope of an individual’s employment. To do so, Bard must be allowed to reference, for example, the fact that its sales representatives sell other products. Finally, Plaintiff does not explain how the relevance of other Bard non-filter products is “*substantially* outweighed” by any danger of unfair prejudice. Plaintiff’s contention that reference to other Bard products would somehow “imply that an adverse verdict against Bard would affect the availability of the other product” has no merit, and there is nothing misleading about explaining to the jury the nature of Bard’s business or the range of activities that its employees undertake. (Doc. 120, at 2.)

## **6. Irrelevant references to experts.**

### **A. References to experts not called to testify in this case.**

This portion of Plaintiff’s Motion is vague, one sentence long, does not describe any specific circumstance in which discussion of experts who are not called to testify would arise, does not say or suggest why a contemporaneous objection would be insufficient to address any concern that Plaintiff may have, and does not describe how or why such references are either irrelevant or how the harm to Plaintiff would substantially outweigh the probative value of such evidence. Thus, there is insufficient information for Bard to respond or for this Court to make a tailored ruling.

By way of example, Drs. Streiff and Garcia proffered joint opinions through a report jointly developed and signed by both experts, but only Dr. Garcia, and not Dr. Streiff, has been identified

as an expert in this case. The same is true of Drs. McMeeking and Begley, where only Dr. McMeeking has been identified as an expert. Given the joint nature of the opinions and reports in this case, Bard must be allowed to ask questions and offer evidence on cross-examination at trial regarding these non-testifying doctors' statements and explanations regarding the opinions contained in the joint reports, if circumstances require. To prevent Bard from so doing would strip Bard of its right to fully cross-examine Plaintiff's experts and to provide the jury with the fullest understanding of Plaintiff's experts' opinions.

**B. References to the number of times an expert has testified in other case [sic] against manufacturers other than Bard.**

The fact Plaintiff's experts have offered opinions that multiple different IVC filters are unsafe or that multiple different IVC filter manufacturers failed to warn doctors about risks concerning the filters is relevant to the weight that the jury should give these experts' opinions about Bard's IVC filters. Additionally, demonstrating that expert witnesses have a pecuniary interest to offer opinions against multiple different IVC filter manufacturers is clearly (1) evidence of witness bias and pecuniary interest, (2) relevant under Rule 401, (3) otherwise admissible, and (4) was permitted in the MDL bellwether trials. *See United States v. Abel*, 469 U.S. 45, 50-51 (1984) (discussing the "state of unanimity" throughout decades of Supreme Court precedent, finding that witness bias is relevant and ripe for cross examination); *In re Bard IVC Filters*, 2018 WL 2095829, at \*5. The Supreme Court defined bias as the "relationship between a party and a witness which might lead the witness to slant, unconsciously or otherwise, his testimony in favor of or against a party," which includes evidence of a witness's "self-interest." *Abel*, 469 U.S. at 52. The Court found that "[p]roof of bias is almost always relevant." *Id.* Further, the Ninth Circuit has found that "[p]ecuniary interest may be shown to prove bias," including the amount of money at

issue, “because the jury may reasonably believe that the willingness of a witness to lie or shade testimony would be affected, not only by whether the results may benefit him, but also by how much.” *United States v. Harris*, 185 F.3d 999, 1008 (9th Cir. 1999) (finding exclusion of witnesses’ pecuniary bias violated defendant’s constitutional rights).

Here, Plaintiff’s experts have offered opinions against various filter manufacturers. These experts, to continue in their roles as plaintiffs’ experts in this and other filter litigation, have a pecuniary interest (indeed, hourly rates far higher than they make in their careers) to opine that Bard’s filters and other manufacturers’ filters are unsafe. Accordingly, testimony about which manufacturers the experts have offered opinions against, the number of manufacturers for which they have offered these opinions against, and the amount of money that they have been paid to offer these opinions are proper and relevant areas of cross-examination. *See, e.g., Shaheen v. Advantage Moving & Storage, Inc.*, 860 N.E.2d 375, 383 (Ill. App. Ct. 2006) (“Courts generally admit evidence that an expert . . . testified for the same attorney in other cases.”); *Goldberg v. Boone*, 912 A.2d 698, 711 (Md. Ct. App. 2006) (holding that “whether the witness is frequently employed by a particular party or attorney [is] appropriate . . . to expose an expert witness’s bias” and admitting evidence that expert had testified in about 25 other cases for plaintiff’s attorney); *Campos v. MTD Prod., Inc.*, No. 2:07-0029, 2009 WL 920337, at \*4 (M.D. Tenn. Apr. 1, 2009) (recognizing relevance of evidence that witness provided “expert services performed on behalf of the defendant and defendant’s counsel in other cases”).

**7. Irrelevant/misleading references re: alleged complaint/failure rates and re: the medical community.**

Evidence of Bard’s internally calculated reporting rates was admitted during every MDL bellwether trial under Rule 803(6) over the MDL plaintiff’s hearsay and Rule 403 objections, the

same objections Plaintiff raises here. (*See, e.g.*, Ex. 2, Trial Tr. at 2349:16 – 2351:2, *Booker v. C. R. Bard, Inc.*, MD-15-02641-PHX-DGC (D. Ariz. Mar. 2018) (“*Booker* Trial Tr.”).) This evidence is equally admissible here for the reasons below.

**A. Bard’s reported complication rates are highly relevant evidence.**

Plaintiff does not dispute the relevance of Bard’s reported complication rates. Indeed, they go directly to the heart of the issues in this case: whether Plaintiff’s Eclipse filter was “too dangerous to be used by anyone,”<sup>5</sup> whether its warnings were adequate, whether its reported failure rates are within those accepted as reasonable by the medical community, and whether the benefits of the device outweigh its risks. Plaintiff raises concerns with the quality of Bard’s data. But Bard has been fully candid in explaining what its reporting rates are, and what they are not. Bard’s former VP for Quality, Mr. Chad Modra, testified that Bard’s calculation of reported IVC filter complication rates is based on the number of reported complaints that Bard uncovers and identifies from multiple sources—which Bard documents in a database, (*see id.* at 2341:2-8; 2348:12-16)—and Bard’s sales data. (*Id.* at 2341:14-20.)<sup>6</sup> Bard recognizes its internally calculated **reporting rates** may not constitute the precise complication rates. (*Id.* at 2352:8-10.) But whether a certain percentage of IVC filter complaints are underreported, as Plaintiff alleges, is of no moment. Bard recognizes underreporting may exist, (*id.* at 2352:25 - 2353:6), and does everything possible to minimize the impact by aggressively investigating all reports of potential complications. Its

<sup>5</sup> Although Bard maintains that this is the applicable standard for Plaintiff’s negligent design claim, (*see* Doc. 93 at 14-17), this evidence is also probative under Plaintiff’s proposed standard as relevant to whether “Bard’s actions in designing the Eclipse Filter deviated from the general standard of care expected under the circumstances.” (Doc. 96 at 7-8.)

<sup>6</sup> Bard anticipates Mr. Modra—or another witness with knowledge—will testify regarding these matters during the trial of this case.

internal calculations reflect the rates of reported complications, and do not purport to reflect the actual complication rate with absolute certitude. (*Id.* at 2347:22 - 2348:8.)

Mr. Modra's testimony confirms the trustworthiness of the data. Bard routinely monitors and trends complication rates, (*id.* at 2340:4-7), and can calculate reported rates at any point. (*Id.* at 2341:2-20.) Bard relies on the reported rate calculations when making risk assessments. (*Id.* at 2259:8-16.) Moreover, Bard has a substantial interest in ensuring the accuracy of its reported rate calculations, given Bard is required under federal regulations to keep and maintain quality system records and to "evaluat[e] complaints by a formally designated unit." 21 C.F.R. § 820.198(a).

**B. Bard's sales figures are relevant and should not be excluded.**

Bard recognizes the number of IVC filters it has sold is not necessarily the same number of IVC filters implanted in patients, and Bard will not represent the same to the jury. Mr. Modra's prior testimony is clear that not all IVC filters sold are actually implanted. (*See* Ex. 2, *Booker* Trial Tr. at 2352:11-13.) Thus, Plaintiff's Motion should be denied as moot. But, as Mr. Modra explains, given the relative price of Bard's filters, the large majority of filters sold are likely implanted. (*Id.* at 2352:14-24.) Also, Bard uses the number of filters sold as the "denominator" to calculate its reported complication rates. (*Id.* at 2341:14-20.) Plaintiff baldly asserts Bard's "total product sales" figures "pose a significant danger of confusing or unfairly prejudicing the jury," but offers no reasoning. (Doc 120 at 12.) The sales figures represent the denominator for Bard's reported rates, evidence that Bard will present in appropriate context and that is highly probative.

**C. Bard does not intend to suggest any specific percentage of doctors use IVC filters.**

Bard has no intention of offering evidence of the specific percentage of doctors who use IVC filters. Thus, Plaintiff's Motion should be denied as moot.

**D. Evidence of the medical community’s knowledge is relevant.**

Bard does not intend to offer evidence about what *all* physicians allegedly know. Thus, Plaintiff’s Motion should be denied as moot. But evidence of what the medical community knows and accepts about IVC filter use and their risks and benefits is directly relevant to Plaintiff’s claims.

**8. Evidence of trade associations or organizations’ opinions for the purpose of supporting legal theories or acceptable rates of complications and safety profiles.**

The SIR Guidelines,<sup>7</sup> and any other evidence of trade associations, societies, or organizations concerning IVC filters and reported complications with IVC filters, were admitted in every MDL trial and are admissible here for the reasons below.

**A. Such material is highly relevant to Plaintiff’s claims.**

Statements of medical societies about IVC filters and reported complications with IVC filters, regardless of the truth of those statements, are relevant to the central issue of whether Plaintiff’s Eclipse was “too dangerous to be used by anyone,” whether its warnings were adequate, whether its reported failure rates are within those accepted as reasonable by the medical community, and whether the benefits of the device outweigh its risks. Indeed, one of Plaintiff’s central claims in this case is that the Eclipse causes higher rates of complication than other IVC filters—including Bard’s Simon Nitinol Filter (“SNF”)—and, thus, Bard’s actions in designing and warning for the Eclipse were not reasonable. This evidence is directly relevant to those claims. For example, the SIR Guidelines, addresses reported rates of filter complications generally seen by physicians as reported in medical literature. The SIR Guidelines discuss the complications of

---

<sup>7</sup> *Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism* published periodically since 2001 by the Society of Interventional Radiology (“SIR”).

fracture, tilt, migration, and penetration of the IVC, citing to medical literature. The jury should be able to consider this evidence when deciding whether the Eclipse was “too dangerous to be used by anyone,” or whether the actions Bard took concerning the design and warnings for Eclipse were reasonable, given that Bard’s reported failure rates were well below those found in the Guidelines. This evidence is equally probative of the jury’s balancing of the risk versus utility of the Eclipse.

Critically, Judge Campbell held, “[t]he SIR guidelines—created by the Society of Interventional Radiologists to inform the medical community regarding acceptable rates of risk in IVC filters—are relevant to the jury’s determination of whether Bard’s [G2X or Eclipse] filter was *reasonably safe*.”<sup>8</sup> *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00893-PHX-DGC, 2018 WL 4215028, at \*4 (D. Ariz. Sept. 4, 2018) (emphasis added). He concluded: “it’s relevant for the jury to understand what doctors knew . . . so that they could decide whether the Bard filters were reasonably safe in the hands of doctors given what doctors knew,” and “part of what doctors knew is the SIR guidelines.” (Ex. 3, *Hyde* Trial Tr. at 1862:20-1863.) Judge Campbell’s reasoning applies equally here.

**B. Such material is admissible as non-hearsay, an exception to hearsay, and as a basis of opinions offered by Bard’s medical experts.**

Despite being rejected in the MDL, Plaintiff again argues that any statement from a medical society is inadmissible hearsay. But Bard intends to use the SIR Guidelines for non-hearsay purposes, including to show notice and the relevant knowledge of the medical community, rather

---

<sup>8</sup> In the first MDL bellwether trial, Judge Campbell deferred ruling on the relevance of statements from medical societies, including the SIR, until trial. *See In re Bard IVC Filters*, 2018 WL 1109554, at \*10. The Court ultimately admitted this evidence in all three MDL bellwether trials. (*See* Doc. 3 at 28-29; Ex. 3, Trial Tr., *Hyde v. C. R. Bard, Inc.*, No. CV-16-00893-PHX-DGC, at 1861:17 to 1865:25 (D. Ariz. Sept. 28, 2018) (“*Hyde* Trial Tr.”).)

than to prove the truth of the matters asserted in the document; therefore, it is not hearsay. Fed. R. Evid. 801(c)(2); David F. Binder, *Hearsay Handbook* § 1:9 (4th ed. 2015) (“[W]hether an out-of-court assertion is hearsay depends on its use” at trial). Courts routinely admit and receive as exhibits “learned treatise” evidence, including medical or scientific literature, when the literature is used for non-hearsay purposes, such as “to establish the . . . knowledge of the medical community.” *Buttice v. G.D. Searle & Co.*, 938 F. Supp. 561, 565–66 (E.D. Mo. 1996). Judge Campbell admitted the SIR Guidelines during the MDL bellwether trials for these exact purposes. (See, e.g., Ex. 2, *Booker* Trial Tr. at 2302:19-2303:10 (admitting SIR Guidelines “for purposes of notice and knowledge within the medical community”); Ex. 3, *Hyde* Trial Tr. at 1861:17-1865:25 (same).) For the following reasons, this Court should too.

**First**, the SIR Guidelines demonstrate what Bard knew at various times regarding the reported and threshold rates of IVC filter complications. Bard’s notice of these rates is directly probative of the whether the actions Bard took concerning the design and warnings for its Eclipse were reasonable. Based on Bard’s notice of these rates in the SIR Guidelines, Bard took various pre- and post-market design and warning related actions, including striving to reduce its complication rates by making improvements from the Recovery to the G2, and by communicating with doctors and FDA regarding Bard’s experiences in relation to the SIR Guidelines.

**Second**, the SIR Guidelines demonstrate the relevant knowledge of the medical community: (1) that filter fracture, migration, perforation, and tilt are well-known complications within the medical community, at least as early as 2001 when the SIR Guidelines were first published; and (2) that these complications have been reported to occur at various rates as documented in the Guidelines. This medical community knowledge is, again, directly probative of

balancing the risk versus utility, and whether the Eclipse was “too dangerous to be used by anyone,” or the actions Bard took concerning the design and warnings for Eclipse were reasonable.

Even if statements by medical societies are offered for the truth of the matter asserted, they reflect statements in learned treatises, periodicals, or pamphlets under Rule 803(18), and therefore are admissible as an exception to the hearsay rule. The SIR Guidelines, when used in the direct examination of Dr. Grassi, clearly fall within the hearsay exception of Rule 803(18). Statements within the Guidelines will be relied upon by Dr. Grassi on direct examination, and he will lay the foundation that the publication wherein the Guidelines are published—the Journal of Vascular and Interventional Radiology—is a “reliable authority.” Fed. R. Evid. 803(18)(A) & (B). Regardless of hearsay, Bard’s medical experts have relied on, and properly disclosed their reliance on, the SIR Guidelines in forming their opinions, and therefore Bard’s experts’ opinions based on the SIR Guidelines are admissible under Rule 703.

**C. The probative value substantially outweighs any danger of prejudice.**

Plaintiff has not explained how the relevance of the SIR Guidelines, as explained above, is “substantially outweighed” by danger of unfair prejudice, confusion of the issues, or misleading the jury. Fed. R. Evid. 403. In fact, *excluding* the SIR Guidelines would risk confusing the jury because many relevant events refer to or relate to the Guidelines, and discussion of them therefore will provide the jury with necessary context. Indeed, Judge Campbell considered and rejected similar arguments. *See In re Bard IVC Filters*, 2018 WL 1109554, at \*10 (rejecting Rule 403 arguments); 2018 WL 4215028, at \*4 (overruling Rule 403 objections; “Plaintiffs’ challenge to their veracity will go to their weight, not their admissibility.”); Ex. 3, *Hyde* Trial Tr. at 1863:4-6 (rejecting similar argument and finding it is not “unfairly prejudicial under Rule 403 because

plaintiffs can bring out the fact that the guidelines are not manufacturing standards”).

**D. Plaintiff misconstrues Dr. Grassi’s testimony.**

The MDL court was similarly unpersuaded by Plaintiff’s misconstruction of Dr. Grassi’s testimony. (Doc. 120 at 13-15.)<sup>9</sup> Dr. Grassi explained the purposes of Table 1 and Table 2 of the SIR Guidelines, and his discussion of Table 2 aligns with the way in which the parties have been using the Table throughout this case.<sup>10</sup> Bard has not, and will not, represent that the SIR Guidelines are established manufacturer “safety thresholds” as Plaintiff falsely claims. Dr. Grassi testified that the trackable events rates contained in Table 2 (which include perforation, migration, and insertion problems like tilt) were intended to provide clinicians with relative rates of the events “as information for readers so they would be able to judge whether or not their adverse events were appropriate, or whether they necessitated further review.” (*See* Ex. 4, Clement Grassi, M.D. Dep. at 769:9 – 770:23.) This information is critical for the jury to put into context Plaintiff’s claims that the Eclipse allegedly had an unacceptably high complication rate. Moreover, these trackable events were for use not just by clinicians but also by those involved with IVC filters more generally. (*Id.* at 204:1 – 205:1.) Dr. Grassi’s testimony confirms that the SIR Guidelines are highly relevant and probative to Plaintiff’s theories of liability in this case.

---

<sup>9</sup> Plaintiff misleadingly quoted to page 769 of Dr. Grassi’s deposition, skipped all of page 770, and quoted page 771. Page 770 concerns the salient testimony about Table 2 of the SIR Guidelines, which refutes Plaintiff’s argument.

<sup>10</sup> The Guidelines contain two tables: Table 1 is a list of “complications,” reported rates, and threshold rates; Table 2 is a list of “other trackable events,” which contains ranges of reported rates for IVC perforation, migration, and insertion problems (which includes tilt) among other complications. The only difference between the Tables is that Table 1 contains the word “Threshold (%)” and Table 2 does not.

**9. Any reference to the number of documents that defendants have produced or the number of current and/or former employees that defendants have produced for depositions.**

Evidence of the number of documents produced by Bard is necessary to impeach Plaintiff's experts at trial and to combat Plaintiff's claims that Bard withheld documents from its salesforce and, as a result, physicians. Bard must be able to counter this narrative by providing necessary context: that the documents presented to witnesses are just a few out of millions of pages of documents, and, therefore, are (1) not documents the witness would have seen in the regular course of business, and (2) not representative of Bard's internal information.

In addition, Bard cannot challenge the sufficiency of the data upon which Plaintiff's experts base their opinions if Bard is precluded from establishing that, in developing their opinions in this case, the Plaintiff's experts failed to review—or were prevented from reviewing—more than just a drop in the bucket of the information available to them. *See* Fed. R. Evid. 705; *see, e.g., In re M & L Bus. Mach. Co., Inc.*, 198 B.R. 800, 812 (D. Colo. 1996) (allowing probing of an expert “for impeachment purposes to show that, in forming his opinions, [he] had not reviewed relevant information to which he had access in the course of his investigation”). Dr. Garcia's testimony illustrates the paucity of the Plaintiff's experts' record review in developing their opinions, is representative of this trend among Plaintiff's experts, and demonstrates Bard's need to expose the same to the jury. (*See* Ex. 5, June 18, 2020 David Garcia, M.D. Dep. at 245:1-246:15 (admitting that, out of the eight million documents produced by Bard, he reviewed approximately 20 selected by Plaintiffs' counsel).)

**10. Any suggestion that Plaintiff was told he needed or should have his filter retrieved from any medical doctor or office or other person prior to Feb. 14, 2015.**

**A. The record evidence clearly indicates that Dr. Goodman chose the Eclipse because he valued the option to retrieve, and was hopeful Plaintiff's Filter could be retrieved.**

Plaintiff's Motion misstates the record evidence. Plaintiff unequivocally testified that, based on conversations with his treating physicians, he was aware his Filter could or should be removed:

Q. Now, do you recall, at the time you had the filter implanted, how long Dr. Goodman told you that the filter should stay in you?

A. No. I remember him saying it was a permanent type of filter, but that given my age, I may want to opt to having it removed in the future.

Q. If I had a medical record that said that the IVC filter will stay in for several months, would you have any basis to disagree with that? Or does that refresh your recollection at all?

A. No, that sounds -- that sounds accurate. I mean, although there was -- you know, there was never a specific date or anything described, that sounds accurate.

(Ex. 6, Jan. 26, 2017 Justin Peterson Dep. at 148:19-149:7; *see also id.* at 149:12-15 ("I remember the suggestion that I not keep it in forever"); Ex. 7, Selected Plaintiff Medical Records at PETERSONJ\_PSVMC\_MDR00034-38 ("[A] temporary filter that he was supposed to get removed but lost insurance and was unable to do so.")).

Dr. Goodman also testified "As part of my preference, because -- especially in a young person, like Mr. Peterson, our goal is to ultimately hopefully -- hopefully be able to remove the filter at some point." (Ex. 8, Mar. 23, 2017 Dr. Jay Goodman Dep. at 64:2-5.) Indeed, Plaintiff's Motion specifically omits the following testimony from Dr. Goodman reflecting his "hope" that the Eclipse would at some point be removed: "Q. So when you placed the Bard Eclipse filter in

Mr. Peterson, did you think it was certainly possible that one day in the future he may have the filter removed? A. Yes, hopeful. You know, he's young.” (*Id.* at 96:1-4.) Nowhere in the testimony Plaintiff cites does Dr. Goodman expressly testify that he would not have evaluated Plaintiff's filter at the scheduled, but not attended, follow-up appointment after June 2010. In fact, Dr. Goodman testified that additional imaging may have been warranted. Dr. Goodman's testimony about his desire to potentially remove Plaintiff's filter is plainly relevant, and the jury is entitled to consider it when evaluating the implication of the scheduled follow-up with Dr. Goodman Plaintiff did not attend. Moreover, the June 27, 2010 record of Plaintiff's discharge plainly notes that his “IVC filter will stay in for several months,” as opposed to permanently. (Ex. 7, at PETERSONJ\_PHHH\_MDR00014-15.) To that end, the jury is entitled to hear the opinions of Defendants' experts, such as Interventional Radiologist Dr. Christopher Morris, regarding the implications of Dr. Goodman's testimony, Plaintiff's missed appointment with Dr. Goodman, and the advisability of earlier retrieval of Plaintiff's filter.

**11. Any suggestion that Plaintiff's filter caught or stopped a clot and saved his life.**

The Court should deny Plaintiff's Motion for three reasons. *First*, the Eclipse Filter's ability to save lives is relevant as it provides the jury with the necessary context about the nature of the product. *See Keen*, 480 F. Supp. 3d at 652 (applying Pennsylvania law) (denying similar motion and concluding that “[w]ithout understanding both the risks and benefits of the filter, the jury would be left without the proper context to understand why Bard would ever design or manufacture IVC filters or why Dr. Sacks implanted the G2X filter in Mr. Keen”). *Second*, “[t]he purpose of Bard's IVC filters and their medical benefits are also relevant to the inquiry of whether Bard violated its duty of care when designing the [Eclipse] filter.” *Id.* at \*4. *Third*, although Mr.

Peterson had an extensive history of blood clots (including a PE) before he received his filter, he never developed a PE while he had a filter. The parties and their experts agree that IVC filters “catch” blood clots that travel up through the IVC and, if no filter is in place, could cause a deadly PE. (Doc. 96 at 3.) That Mr. Peterson did not experience a PE while he had his IVC filter implanted is neither “speculative” nor “unduly prejudicial,” it is a relevant and highly probative fact.

Plaintiff cites the deposition testimony of Janet Hudnall, BPV’s former senior Marketing Manager, for the proposition that “there is no way to know” if an IVC filter “catches” a clot “unless monitored with a scan in real time as it happens.” (Doc. 120, at 17.) Ms. Hudnall’s referenced testimony simply states, accurately, that it is not possible to determine the exact number of clots that Bard’s filters have “caught” over time and stopped from entering the heart or lungs. (Ex. 9, Nov. 1, 2013 Janet Hudnall Dep. at 138:6–11.) She explains that this is because patients with Bard’s IVC filters could be living life unaware that their filter contains a clot burden which, absent the filter, may have led to a deadly PE. If anything, Ms. Hudnall’s testimony highlights precisely why Bard should be able to tell the jury that Mr. Peterson’s Eclipse Filter may have prevented a deadly PE; Plaintiff’s conclusory argument that such evidence is “speculative” goes to its weight, not its admissibility. *See Keen*, 480 F. Supp. 3d at 652 (“challenges to Bard’s evidence would be more appropriately addressed through vigorous cross examination, not exclusion”).

**12. Any reference to any family history of blood clots and deep vein thrombosis.**

Reference to Plaintiff’s family history of DVT/clotting disorders, including that his grandmother suffered from DVT and was prescribed lifelong Coumadin and Warfarin when Plaintiff was a child, is relevant not only to provide a full picture of Plaintiff’s medical history the jury is entitled to receive, but also to inform Plaintiff’s knowledge and state of mind regarding the

strict protocols for Coumadin compliance, which is a clear issue in this case. Plaintiff's "thin skull" argument is irrelevant because the evidence at issue would not be offered to establish the adequacy of either warnings or design. Rather, such evidence is probative of Plaintiff's awareness, since childhood, of the seriousness of clotting disorders and the necessity of routine follow up, issues that go to Plaintiff's own culpability in failing to have his filter evaluated at an earlier date. Plaintiff has not argued, and cannot argue, that such evidence would pose any risk of prejudice, let alone the unfair prejudice required under Rule 403. Therefore, Plaintiff's Motion should be denied.

**13. Any reference to Mr. Peterson's use of substances.**

Bard incorporates by reference its opposition to Plaintiff's *Daubert* motion to exclude certain opinions of Dr. Christopher Morris filed contemporaneously herewith, which addresses this issue. Moreover, it is flatly untrue that Dr. Morris is the only "medical witness who has opined that smoking or alcohol ingestion has had any effect on the injuries at issue in this lawsuit." (Doc. 120 at 18.) Mr. Peterson's substance use is directly relevant to his hematological profile, including his Coumadin compliance, which is a central element in this case bearing on his necessity for an IVC filter among other issues. Indeed, a medical record signed by Dr. Dhatt Ravinder on November 20, 2009 states: "Hematology was consulted and Ativan PRN for precautions because of history of alcoholism was also started." (Ex. 7, at PETERSONJ\_PHHH\_MDR00124.) Mr. Peterson likewise testified he was fully aware that his use of substances such as alcohol, and the consistency of his use of those substances, could impact his Coumadin protocol. (*See* Ex. 6, Peterson Dep. at 110:18-111:7.) Bard is entitled not only to raise these issues affirmatively, but to cross examine Plaintiff's witnesses, including his experts, to determine whether they considered these issues in evaluating Plaintiff's clotting disorder and alleged injuries. Bard is likewise entitled

to cross examine Plaintiff on his purchase and consumption of substances to the extent he argues he could not afford insurance, which precluded him from seeking medical evaluation of his filter earlier than he did. Finally, Plaintiff's prejudice argument is plainly overblown. The record evidence of Plaintiff's alcohol consumption does not shock the conscious, and Plaintiff is unlikely to suffer any prejudice, let alone unfair prejudice, if such evidence is adduced to shed light on important aspects of his medical history. Therefore, Plaintiff's Motion should be denied.

**13. [sic]<sup>11</sup> Any reference to Mr. Peterson's consumption of alcohol as the cause of his hypercoagulable state.**

Bard incorporates by reference its opposition to Plaintiff's *Daubert* motion to exclude certain opinions of Dr. Morris filed contemporaneously herewith, which addresses this issue.

**14. References to or assertion of the "Empty Chair" defense.**

Bard should not be precluded from referencing the relevant conduct and actions of Plaintiff and others who have not been named as parties and will not appear on the verdict form. Plaintiff seeks to exclude Bard from "making any reference to Mr. Peterson or any non-party as causing or contributing to any injuries at issue in this case" because Pennsylvania law does not permit allocation of fault to a non-party. (Doc. 120 at 19.) As an initial matter, under Pennsylvania negligence law the jury can unquestionably consider the contributory fault of Plaintiff, who *is* a party to this action. *See generally* 42 Pa. Cons. Stat. Ann. § 7102. Thus, Plaintiff's contention that Bard should be precluded from any reference to Mr. Peterson's action causing or contributing to his own injuries because it is not relevant is misplaced.

---

<sup>11</sup> Plaintiff includes a second motion *in limine* no. "13." Bard notes this error with "[sic]." To avoid confusion, however, Bard responds to the remaining motions *in limine* as numbered.

Additionally, while Bard recognizes Plaintiff's treating physicians are not defendants and will not appear on the verdict form, testimony and evidence regarding their treatment decisions is necessary to explain the basis for Bard's expert's opinions regarding the Plaintiff's need for an IVC filter in the first place and when it could have feasibly been removed. Moreover, although Bard cannot apportion liability on the verdict form to the treating physicians as non-parties, Bard should not be precluded from asserting that Plaintiff cannot meet *his* burden of establishing proximate cause for the damages alleged. Importantly, as to proximate cause, a defendant "carries no burden of proof." *Kennedy v. Sell*, 816 A.2d 1153, 1158 (Pa. Super. Ct. 2003). Thus, testimony and evidence offered not to prove that injuries were caused by one particular source, but rather to show that the plaintiff cannot demonstrate the causal connection he or she bears the burden of establishing, is relevant and appropriate. *See id.* at 1159.

**15. Any reference to or evidence of a collateral source having paid any of Mr. Peterson's expenses or damage related to the injuries at issue.**

Bard does not intend to affirmatively introduce evidence of collateral sources unless an exception to the collateral source rule applies pursuant to Pennsylvania law. *See, e.g., Coney v. NPR, Inc.*, No. CIV A 03-1324, 2006 WL 2601507, at \*4 (E.D. Pa. Sept. 11, 2006) ("[I]f evidence in plaintiffs' case is offered to show financial hardship and if that evidence could fairly be met by evidence of the receipt of workers' compensation benefits, the Court will give serious consideration to allowing this evidence to come in.").

Plaintiff's Motion regarding collateral source evidence erroneously assumes that Oregon law applies to the issue of compensatory damages and the potential application of the collateral source doctrine. (Doc. 120, at 20.) This Court already held that "Pennsylvania law governs the issues presented in this case. The *one* exception is Mr. Peterson's claim for punitive damages, to

which Arizona law applies.” (Doc. 73 at 18 (emphasis added).) This Court recognized the Oregon Law Commission’s caution to avoid unnecessary splitting of the case, noting that the “only logical way” to split the issues is to “split the issue of punitive damages from the issues of product liability and compensatory damages,” but to decline further splitting. (*Id.* at 7.)

Plaintiff seeks to apply Oregon law, presumably so he can submit into evidence the amount of his *billed* medical expenses (allegedly \$173,349.58). (*See* Doc. 95.) Under Pennsylvania law, “the amount *paid* and accepted by [the provider] as payment in full for the medical services is the amount [the Plaintiff] is entitled recover as compensatory damages.” *Moorhead v. Crozer Chester Med. Ctr.*, 765 A.2d 786, 789 (Pa. 2001) (emphasis added), *overruled on other grounds*, *Northbrook Life Ins. Co. v. Com.*, 949 A.2d 333 (Pa. 2008). The amount *paid* by Plaintiff’s insurers for his alleged medical expenses is \$95,624.41 (a difference of \$77,725.17). (*See* Doc. 95.)

**16. Reference that Bard was precluded from sending warning letters, changing the instructions for use to add or strengthen a warning regarding the risks of migration, perforation, and/or death associated with its IVC filters, or effectuating a removal/recall without the consent of the FDA**

**A. Bard cannot include in its labeling comparative rate information or increased risks warnings based solely on MDR or MAUDE Data, and Plaintiff has proffered no purported “other reliable sources” to support his proposed warnings.**

Bard will not argue that it could never modify its IFU without FDA consent. As discussed below, what Bard will argue, and is entitled to argue under the Federal Rules of Evidence, is that the changes to the IFU contemplated by Plaintiff are based on insufficiently reliable data and fall outside the realm of possible changes that Bard could effectuate without FDA clearance.

FDA reviewed and cleared Bard’s labeling for its IVC filters as part of the 510(k) clearance

process,<sup>12</sup> including the Eclipse that Plaintiff received. Critically, Plaintiff acknowledges that Bard cannot include in its labeling his proposed comparative rate information or “increased risks” warnings based on medical device reports (“MDRs”) or MAUDE data alone. (Doc. 120 at 22.) He concedes that FDA specifically states that “MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.”<sup>13</sup> (*Id.*) In fact, when Dr. Suzanne Parisian—the Plaintiff’s regulatory expert—was asked “you would not put the comparison based only on the MAUDE database into your labeling, would you?” she responded, “No. You could use medical literature . . . But the MAUDE database, it can be used for certain things, but it’s not -- you wouldn’t use it across industry to come up with the incidence rate.” (Ex. 10, Sept. 25, 2014 Dr. Suzanne Parisian Dep. at 71:5-18.) The spontaneously reported MDRs in the MAUDE database are simply insufficient standing alone to compare incidence rates; and, thus, Bard could not include any proposed warnings about comparative or increased rates in its labeling based solely on this data. Just as Judge Campbell ruled in the MDL, Bard should be permitted here to “present evidence and argument explaining ... *the fact* that warnings about failure rates and increased risks could not be based on MDR and MAUDE data alone.” *In re Bard IVC Filters*, 2018 WL 1109554, at \*12 (emphasis added); (*see* Doc. 3 at 28).

As Plaintiff notes, Judge Campbell recognized that Bard could “provide a warning about

---

<sup>12</sup> Although Plaintiff discusses the 510(k) clearance process and substantial equivalence here, this Motion is limited to arguments about post-market labeling changes. Plaintiff’s arguments about the admissibility of evidence related to FDA’s 510(k) review are addressed in Bard’s opposition to Plaintiff’s separate Motion *in Limine* No. 18 to Preclude FDA Evidence, *infra*.

<sup>13</sup> *See* <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>.

increased risks based on other reliable sources.” (Doc. 120 at 22.) But the only purported “other reliable source” of increased risks that Plaintiff proffers is Bard’s March 2004 internal bench testing relating to migration in the Recovery Filter (Bard’s first-generation IVC filter), *not* the Eclipse (Bard’s fourth-generation IVC filter) at issue in this case. (*Id.* at 23 n.32.)<sup>14</sup> This Recovery migration testing is completely irrelevant to warnings concerning Plaintiff’s Eclipse, which incorporated significant design changes aimed specifically at migration resistance—design changes that worked. *In re: Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00782-PHX-DGC, 2018 WL 1993767, at \*2 (D. Ariz. Apr. 27, 2018) (“[C]ephalad migration deaths stopped after the Recovery”). Bard should be permitted to present evidence and argument that FDA expects device labeling to be based on relevant, scientific, and reliable sources, and that irrelevant internal testing about an entirely different device is not the sort of reliable source of “increased risks” as to the Eclipse that Bard should have revised its warnings to include (as Plaintiff advocates).

**B. Bard does not intend to suggest that it was precluded from sending warning letters to physicians.**

Bard does not intend to offer evidence to suggest that it could not send warning letters to physicians. To the contrary, Bard has sent Dear Doctor Letters to physicians concerning its IVC filters in the past. Thus, Plaintiff’s Motion should be denied as moot. But FDA’s own actions with Bard demonstrate that it expects manufacturers to collaborate with the agency in drafting and revising its labeling and Dear Doctor Letters before instituting any changes. Indeed, FDA was heavily involved in post-market revisions of Bard’s labeling and a Dear Doctor Letter that Bard

---

<sup>14</sup> Plaintiff also claims that Bard should have added warnings about “numerous negative facts relating to its IVC Filters, including the Eclipse[,], Recovery, G2, and G2X,” but does not articulate these “facts” or the language of his proposed warnings, nor does he identify any “reliable source” to support its inclusion. (Doc. 120 at 24.)

planned to send, as well as review of a Dear Colleague Letter. Bard should be entitled to explain FDA's involvement in the review of its post-market labeling changes, including these Letters. Bard should also be entitled, as Judge Campbell recognized, to present evidence and argument why such letters "could not be based on MDR and MAUDE data alone." *In re Bard IVC Filters*, 2018 WL 1109554, at \*12. Bard should further be allowed to present evidence and argument why the comparative rate and increased risks information that Plaintiff argues Bard should have provided in revised warnings and in letters to physicians are not based on "reliable sources."

**C. Bard does not dispute that a manufacturer may voluntarily initiate a recall but there is an important role for FDA in the recall process.**

Bard does not dispute that a medical device manufacturer can voluntarily initiate a product recall pursuant to 21 C.F.R. § 7.46.<sup>15</sup> Thus, Plaintiff's Motion should be denied as moot. But it is undisputed that there is an important role for FDA in the voluntary recall process under § 7.46, which clearly notes several agency actions that never happened with Bard's IVC filters. In particular, § 7.46(a) states that "[s]uch removal or correction will be considered a recall only if the [FDA] regards the product as involving a violation that is subject to legal action." Further, § 7.46(c) states that "[a] firm may decide to recall a product when informed by the [FDA] that the agency has determined that the product in question violates the law." And in situations where § 7.46(d) applies, "the [FDA] will assist the firm in determining the exact nature of the problem." *Id.*

The fact that FDA requires that manufacturers work with the agency when implementing voluntary recalls is critical to put into context Plaintiff's claim that Bard independently should

---

<sup>15</sup> Bard takes no position on whether evidence or argument on whether a recall was required in this case is probative or admissible at this point, but reserves its right to raise such objections at trial.

have voluntarily recalled any of its IVC filters.<sup>16</sup> Thus, Bard should be permitted to offer evidence of why its IVC filters were not recalled, including the fact that (a) FDA never suggested Bard should voluntarily recall its IVC filters due to complications; (b) FDA never mandated a recall<sup>17</sup>; and (c) Bard could not have effectuated a recall without FDA involvement.

Judge Campbell agreed and ruled in the MDL bellwether trials that Bard may “present evidence and argument explaining the reasons why Bard filters were not recalled, [and] the FDA’s potential involvement in any recall effort.” *In re Bard IVC Filters*, 2018 WL 1109554, at \*12; *see also id.* at \*10 (“Defendants may, however, present evidence and argument explaining the FDA’s potential involvement in any recall effort and the reasons why Bard filters were not recalled.”).

**17. Argument and evidence regarding the Surgeon General’s 2008 call to action.**

Plaintiff slightly revises the language of his motion from the version rejected in the MDL and adds a single, new unpersuasive citation to a Fifth Circuit case. But the essence of his motion remains the same: that the Surgeon General’s Call to Action is hearsay, irrelevant, and prejudicial. Judge Campbell considered this document, considered these arguments, and determined that the report (1) “falls within the public records hearsay exception,” (2) “is relevant to the risk-benefit analysis because it explains the benefits of IVC filters,” and (3) would not “confuse the jury or

---

<sup>16</sup> Of note, Plaintiff misconstrues Ms. Hudnall’s testimony regarding the transition from the Recovery to the G2 Filter. The Recovery was not voluntarily recalled as Plaintiff implies, and Ms. Hudnall’s preceding testimony, which Plaintiff omits, clarifies that the Recovery was not taken off the market because of complication rates, but that “[t]he G2 filter was the next generation of the Recovery filter. So [Bard] didn’t keep previous generation and new generation at the same time.” (Ex. 9, Hudnall Dep. at 135:5-14.)

<sup>17</sup> FDA has the power to mandate a medical device recall pursuant to 21 C.F.R. § 810.10, which provides that FDA may “issue a cease distribution and notification order” to a manufacturer. *See also* FDA’s Regulatory Procedures Manual at Section 7-5-3 (entitled “FDA Mandated Recalls”), *available at* <https://www.fda.gov/media/71814/download> (last accessed Apr. 6, 2021).

unfairly prejudice Plaintiffs.” *In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00893-PHX-DGC, 2018 WL 4279833, at \*3 (D. Ariz. Sept. 7, 2018). Tellingly, Plaintiff still does not cite a single case excluding a Surgeon General’s Report under the Federal Rules of Evidence.

**A. The Surgeon General’s Call to Action is admissible under the public records hearsay exception.**

The single new citation added by Plaintiff is *Jacobs v. Leblanc*, 639 F. App’x 252, 253 (5th Cir. 2016), which Plaintiff misleadingly describes as “holding that exclusion of surgeon general report objected to as irrelevant and inadmissible hearsay was not an abuse of discretion.” (Doc. 120 at 35.) Contrary to Plaintiff’s description, “[t]he article *is not* from the 2006 U.S. Surgeon General’s Report but rather appears to be a document from the Americans for Nonsmoker’s Rights which purportedly repeats the report’s conclusion.” *Jacobs v. LeBlanc*, No. 3:10-CV-00271-JWD, 2015 WL 364170, at \*4 (M.D. La. Jan. 26, 2015), *aff’d*, 639 F. App’x 252 (5th Cir. 2016) (emphasis added). Thus, the district court was affirmed in its decision that “while these statements [in the article] *are relevant* to the issue of damages, they are hearsay *within hearsay*, and no exception appears to apply. Further, they are not properly authenticated.” *Id.* (emphasis added).

Similarly, Plaintiff continues to rely on *Philip Morris USA, Inc. v. Pollari*, 228 So. 3d 115 (Fla. 4th DCA 2017) for the proposition that “the court considered Surgeon General Reports about tobacco, found them inadmissible, and further concluded that admitting the reports was not harmless error.” (Doc. 120 at 34.) As he did in the MDL, Plaintiff omits that the *Pollari* court found that Surgeon General Reports were inadmissible hearsay under the Florida Rules of Evidence, but explicitly found that, unlike the Florida Rules, the Surgeon General’s reports at issue would be *admissible* under the Federal Rules:

The Surgeon General's Reports clearly fit only under that third category found in the Federal Rules as records relying on information supplied by outside sources and gathered during an investigation. The United States Court of Appeals for the Eighth Circuit in *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594, 600 (8th Cir. 2005), reached that same conclusion when it affirmed a district court's admission of several Surgeon General Reports on smoking as public records falling under that third category. The Eighth Circuit concluded that even though the reports included factual findings "made by independent scientists and not on the basis of independent research by the Surgeon General," they were admissible because they were prepared by "a disinterested governmental agency" pursuant to a legal obligation "to report new and current information on smoking and health to the U.S. Congress." However, as [Florida precedent] instructs, **while such records may be admissible under the rules of the federal court system**, they are clearly inadmissible under the Florida Evidence Code."

*Pollari*, 228 So. 3d at 123 (emphasis added). Thus, this Court should find that under the Federal Rules, and consistent with the rulings in all three MDL bellwether trials, the Call to Action is a trustworthy public record.<sup>18</sup> See, e.g., Surgeon General's Calls to Action, available at <https://www.surgeongeneral.gov/library/calls/index.html> (last visited Apr. 1, 2021) (emphasis added) ("Surgeon General Calls to Action are *science-based summary documents* intended to stimulate action nationwide to solve an urgent public health problem . . . Surgeon General's advisories are *public statements*, on a public health issue, that provide evidence-based recommendations to the public.").

**B. The Surgeon General's Call to Action is relevant, not prejudicial, and will not mislead the jury.**

Plaintiff's complaints of prejudice echo his arguments to exclude evidence of FDA's

---

<sup>18</sup> Plaintiff also suggests that *Gruca v. Alpha Therapeutic Corp.*, 51 F.3d 638 (7th Cir. 1995) holds that the Call to Action should be excluded because it improperly suggests "that federal government's action 'absolved the defendants from liability for negligence.'" (Doc. 120 at 34.) However, *Gruca* was based on the defense counsel's closing argument that the plaintiff "selected the defendants" and "could have sued the FDA." This was a "misstatement[] of law [because] the FDA is immune from suit." *Id.* at 645. The improper statement in *Gruca* does not remotely resemble Bard's use of the Call to Action.

510(k) clearance process and the SIR Guidelines, which he similarly raises again here despite already being rejected by the MDL court. Again, Plaintiff seeks to exclude evidence of a prominent public health entity recognizing IVC filters as an appropriate treatment option. But, Plaintiff does not point to any legitimate prejudice from Bard's limited use of the Call to Action. Instead, Plaintiff includes extensive quotations of other portions of the Call to Action *never* referenced by Bard.<sup>19</sup> As the MDL court noted, "[t]he record does not support Plaintiffs' assertion that Defendants argued during the first two bellwether trials that 'Bard acted at the direction of the Surgeon General' and 'the Surgeon General considers Bard's IVC filters necessary' to treat pulmonary emboli. If Plaintiffs believe that Defendants are improperly implying the imprimatur of the Surgeon General, they may object at trial. But the Court cannot conclude that admission of the Call to Action report will confuse the jury or unfairly prejudice Plaintiffs." *In re Bard IVC Filters*, 2018 WL 4279833, at \*3. Plaintiff continues to use a "straw-man" because there is no legitimate basis to exclude the Call to Action. *McHenry v. PacificSource Health Plans*, 679 F. Supp. 2d 1226, 1237 (D. Or. 2010), *adhered to in relevant part on reconsideration*, No. CV-08-562-ST, 2010 WL 11699617 (D. Or. Sept. 28, 2010) (relying on a 1999 Surgeon General's Report on mental health, among other sources, to find that a treatment method was "firmly supported by decades of research and application").<sup>20</sup>

<sup>19</sup> Indeed, Plaintiff provides a litany of examples of increased risk for DVT and PE that are clearly inapplicable to Mr. Peterson such as pregnancy, and specifically omits genetic predispositions, such as Mr. Peterson's May-Thurner syndrome. (Doc. 120 at 32.)

<sup>20</sup> The Ninth Circuit regularly considers Surgeon General's Reports on a variety of topics. *See, e.g., Ledezma-Cosino v. Sessions*, 857 F.3d 1042, 1053 (9th Cir. 2017) (citing *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health* (2016)); *Soliman v. Philip Morris Inc.*, 311 F.3d 966, 969 (9th Cir. 2002) (citing the *Surgeon General's Report on The Health Consequences of Smoking: Nicotine Addiction* (1988)); *Baker v. Adventist Health, Inc.*, 260 F.3d 987, 997 (9th Cir. 2001) (citing *Mental Health: A Report of the Surgeon General* (1999));

Rather, the Call to Action goes directly to the required design defect analysis. Under Pennsylvania law, a manufacturer is only liable if it supplies a product that it “knew or reasonably should have known is too dangerous to be used by anyone.” PBI, *Pennsylvania Suggested Standard Civil Jury Instructions*, at 23.40 (4th ed. 2018 supp.); *Lance v. Wyeth*, 85 A.3d 434, 461 (Pa. 2014); *see also Keen*, 480 F. Supp. 3d at 638-39. The Call to Action—which includes references to 97 different pieces of medical literature collected by the Surgeon General’s office and reflects the knowledge of health care providers and governmental public health entities at the time—goes directly to that analysis. Indeed, in this context, the Call to Action is not hearsay at all under Federal Rule of Evidence 801(c)(2).

Moreover, the Call to Action is one more piece of evidence to rebut Plaintiff’s claims that IVC filters, including Bard’s filters, provide no clinical benefit, and are not safe or effective. Indeed, Plaintiff designated Dr. Garcia to specifically argue to the jury that anticoagulants are superior to IVC filters to treat PE – **all** IVC filters, not just Bard’s filters. Also, Plaintiff’s central themes include (1) that the FDA and medical community were unaware of the risks posed by Bard’s IVC filters, and (2) that Bard’s retrievable filters should have had the same safety profile of permanent filters such as the SNF. The Call to Action provides context to rebutting this assertion, in that the Surgeon General calls for the health care system to further “research the risks and benefits related to permanent versus retrievable placement of IVC filters.” (Doc. 120-22 at 38.) Plaintiff asks this Court to allow him to present evidence to the jury that Bard, and only Bard, knew of risks associated with its IVC filters, yet deprive Bard from presenting evidence regarding

---

*Chalk v. U.S. Dist. Ct. Cent. Dist. of California*, 840 F.2d 701, 706 (9th Cir. 1988) (citing *Surgeon General’s Report on Acquired Immune Deficiency Syndrome* (1986)).

widespread knowledge and acceptance of those risks in the medical community. It would be fundamentally unjust for Plaintiff's request to be granted.

**18. References to that clearance of Bard IVC filters by the FDA and/or lack of FDA enforcement action regarding same constitutes proof of safety and/or efficacy.**

The issues presented in Plaintiff's Motion were decided under substantially similar facts and law in the MDL. Indeed, Judge Campbell considered extensive briefing on this very issue, ruled in Bard's favor, and discussed his ruling in his Transfer Order. *See In re Bard IVC Filters Prods. Liab. Litig.*, 289 F. Supp. 3d 1045 (D. Ariz. 2018); (*see* Doc. 3 at 21-22). Applying Georgia law, Judge Campbell found Bard's compliance with federal regulatory standards, such as FDA's 510(k) clearance process, and the lack of FDA enforcement action, is "relevant to the reasonableness of Bard's conduct" and whether the filter is "defectively designed." *Id.* at 1047. Subsequently, the *Keen* court in Pennsylvania applied the same reasoning and reached the same result as to negligent design and warnings claims under Pennsylvania law. *See Keen*, 480 F. Supp. 3d at 650-51. In his Motion, Plaintiff fails to inform the Court of the *Keen* decision—he ignores it altogether—and attempts in a mere footnote to distinguish Judge Campbell's well-reasoned opinion, baldly arguing without any support that this evidence is irrelevant under Pennsylvania law and asserting the same arguments that the MDL and *Keen* courts rejected.<sup>21</sup> As the *Keen* decision makes clear, this evidence is directly relevant to the very claims and law that Plaintiff is pursuing at trial and, thus, the MDL and *Keen* courts' analyses apply equally here. Plaintiff raises

---

<sup>21</sup> Although Plaintiff acknowledges that Judge Campbell denied a similar motion, Plaintiff repeatedly misquotes Judge Campbell's decision in a parenthetical leaving the misimpression that the MDL court, purportedly quoting from *Cisson*, "exclud[ed] 510(k) evidence 'because of its tendency to mislead the jury and confuse the issues.'" (Doc. 120 at 33, 36.) This quote is found nowhere in Judge Campbell's decision; to the contrary, he found such evidence to be both relevant and admissible. *See, e.g., In re Bard IVC Filters*, 289 F. Supp. 3d at 1047.

no new arguments concerning the relevance of this evidence, or as to why he will somehow be prejudiced by its admission. This Court should deny Plaintiff's Motion.

**A. Factual Background.**

Bard's Eclipse Filter is a Class II medical device that FDA cleared before Bard was permitted to market the device. FDA's mission, carried out in relevant part by its regulatory review of products, is to ensure that devices cleared for market are both safe and effective. While the level of regulatory review may vary depending on the class of product involved, it is fundamentally wrong to suggest that the 510(k) process does not consider safety and effectiveness. According to FDA, "*the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review.*"<sup>22</sup> "The FDA grants 510(k) clearance only where the device 'is as safe and effective as a [predicate device] and does not raise different questions of safety and efficacy than the predicate device.' Safe Medical Devices Act of 1990 ['SMDA'].<sup>23</sup> *In re Bard IVC Filters*, 289 F. Supp. 3d at 1048. "The SMDA did introduce safety and effectiveness considerations into 510(k) review," even if the standard for those considerations is comparative. *In re Bard IVC Filters Prod. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2017 WL 5625547, at \*7 (D. Ariz. Nov. 22, 2017), *aff'd*, 969 F.3d 1067 (9th Cir. 2020).

FDA originally classified IVC filters as Class III devices. *See* 45 Fed. Reg. 17736 (FDA Feb. 5, 1980). Beginning in 1995, FDA required IVC filter manufacturers to submit summaries of known safety and effectiveness information for FDA to determine whether to reclassify the devices.<sup>23</sup> On December 2, 1996, after an "extensive review" of all the publicly available

<sup>22</sup> (Ex. 11, FDA Guidance "*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*," issued July 28, 2014, at 6.)

<sup>23</sup> (*See* Ex. 12, Dec. 2, 1996, FDA Reclassification of Cardiovascular IVC Filters.)

information, MDRs, previously cleared 510(k)s, and the information submitted by manufacturers concerning the risks and benefits of IVC filters, FDA identified all of the known safety and efficacy concerns for IVC filters. (*See* Ex. 12, at 4-7 (internal pp. 68-71).) FDA found that, “[a]lthough these risks are potentially life threatening, as is the disease they are intended to treat, they are well known to the users and are well characterized in the medical literature.” (*Id.* at 3 (internal p. 67).) FDA also identified the competing benefits of IVC filter use. (*Id.* at 7-8 (internal pp. 71-72).)

Weighing those benefits against risks that “have been well characterized” over the long history of IVC filter use, FDA concluded “that the use of [IVC filters for certain indications] does not present a potential unreasonable risk of illness and injury, and that special controls would ***provide reasonable assurance of the safety and effectiveness of the device.***” (*Id.* at 3-4 (emphasis added) (internal pp. 67-68).) “Although placement of IVC filters are not without risks, the likelihood of risks occurring is relatively small and special controls will further minimize these occurrences.” (*Id.* at 8 (internal p. 72).) “Special controls in the form of standardized labeling and a device [Guidance] on vena cava filters..., in addition to general controls, ***provide reasonable assurance of the safety and effectiveness of the device.***” (*Id.* at 3 (emphasis added) (internal p. 67).) Thus, FDA concluded, “based on publicly available, valid scientific evidence, the [IVC] filter can be regulated as a Class II device (general and special controls) to ***reasonably assure that the device is safe and effective for its intended use.***” (*Id.* at 8 (emphasis added) (internal p. 72).)

In a final rule dated March 31, 2000, *see* 65 Fed. Reg. 17138, 17144 (FDA Mar. 31, 2000), FDA down-classified IVC filters from Class III to Class II, amending 21 C.F.R. § 870.3775 and incorporating special controls, including an FDA Guidance document entitled “Guidance for Cardiovascular Intravascular Filter 510(k) Submission,” that was intended to identify important

preclinical tests and clinical design considerations for these devices.<sup>24</sup>

The Eclipse is part of Bard's G2 line of filters, which also includes the G2, G2 Express, and G2X.<sup>25</sup> Plaintiff acknowledges that Eclipse was cleared as substantially equivalent to the G2X, which itself was cleared as substantially equivalent to the G2, (Doc. 120 at 39), and goes to great lengths to argue in his briefing that the Eclipse is not meaningfully different from the G2. (*Id.* at 23-25.) The regulatory record in this case (which is the same record before the MDL and *Keen* courts) shows that FDA did consider the safety and efficacy of the G2 line of filters before clearing them. For example, before Bard could market the device as a permanent filter, FDA demanded specific safety and effectiveness information concerning Bard's animal studies, mandated specific revisions to the labeling, and even required Bard to change the trade name of the device for safety and effectiveness reasons.<sup>26</sup> Additionally, given FDA's questions about retrievability, FDA required Bard to conduct an IDE clinical trial called "EVEREST."<sup>27</sup> FDA also requested that this clinical trial assess the product's safety performance, including, specifically, migration. Between 2005 to 2008, Bard and FDA exchanged numerous communications concerning the EVEREST

<sup>24</sup> (See Ex. 13, November 26, 1999, Guidance for Industry and FDA Staff: Guidance for Cardiovascular Intravascular Filter 510(k) Submission.)

<sup>25</sup> The G2 and G2 Express/G2X are identical except that the G2 Express/G2X include a snarable "hook" at the apex of the devices. The Eclipse is identical to the G2 Express/G2X except that it has an electropolished surface finish.

<sup>26</sup> (See Ex. 14, Mar. 30, 2005 Letter from FDA to BPV; Ex. 15, Apr. 19, 2005 Letter from BPV to FDA; Ex. 16, May 2, 2005 Internal FDA Review Memo; Ex. 17, June 3, 2005 Letter from BPV to FDA; Ex. 18, July 26, 2005 Internal FDA Review Memo; Ex. 19, July 26, 2005 FDA Contact Report; Ex. 20, July 28, 2005 Letter from FDA to BPV; Ex. 21, Aug. 10, 2005 Letter from BPV to FDA; Ex. 22, Aug. 22, 2005 Internal FDA Review Memo; Ex. 23, July 28, 2005 FDA Contact Report; Ex. 24, Aug. 26, 2005 Fax from FDA to BPV; Ex. 25, Aug. 29, 2005 Fax from BPV to FDA; Ex. 26, Aug. 29, 2005 Email from BPV to FDA; Ex. 27, Aug. 29, 2005 FDA Clearance.)

<sup>27</sup> (See Exs. 14-18; Ex. 28, Mar. 24, 2005 FDA Contact Report; Ex. 29, Mar. 29, 2005 Internal FDA Memo; Ex. 30, May 6, 2005 FDA Contact Report; Ex. 31, May 27, 2005 FDA Contact Report.)

trial.<sup>28</sup> FDA demanded information about adverse events observed during the trial.<sup>29</sup> Bard complied and also provided information to FDA regarding the clinical effectiveness and success of retrievability of the G2.<sup>30</sup> FDA reviewed all of the data from the clinical study and information concerning adverse events observed during the trial and cleared the G2 as safe and effective for retrievability on January 15, 2008.<sup>31</sup> FDA subsequently cleared the G2 Express in July 2008, and the G2X in October 2008.<sup>32</sup>

Before Bard could market the Eclipse, FDA required Bard to conduct additional testing for radial force, tensile strength, and migration/clot trapping, which Bard did.<sup>33</sup> FDA cleared the Eclipse in January 2010.<sup>34</sup> Bard made subsequent changes to the Eclipse labeling to add a patient brochure and implant card, which FDA reviewed and substantively edited. FDA also required that Bard provide additional information.<sup>35</sup> After Bard revised the label and provided the information, FDA cleared the device and the accompanying brochure in June 2010.<sup>36</sup>

**B. FDA's clearance of the Filter is relevant under Pennsylvania law.**

Evidence of Bard's compliance with federal regulatory standards, while not dispositive, is relevant to Plaintiff's negligence claims under Pennsylvania law. *Keen*, 480 F. Supp. 3d at 650

<sup>28</sup> (*See, e.g.*, Ex. 32, Aug. 23, 2007 EVEREST Annual Progress Report.) Bard does not attach all of the voluminous communications, IDE supplements, and annual progress reports over this three-year period, but stands ready to do so at the Court's request.

<sup>29</sup> (Ex. 33, Sept. 21, 2007 Letter from FDA to BPV.)

<sup>30</sup> (Ex. 34, Oct. 25, 2007 Letter from BPV to FDA.)

<sup>31</sup> (Ex. 35, Jan. 15, 2008 FDA Clearance.)

<sup>32</sup> (Ex. 36, July 30, 2008 FDA Clearance; Ex. 37, Oct. 31, 2008 FDA Clearance.)

<sup>33</sup> (Ex. 38, Dec. 15, 2009 Letter from FDA; Ex. 39, Dec. 17, 2009 Letter from Bard to FDA.)

<sup>34</sup> (Ex. 40, Jan. 14, 2010 FDA Clearance.) Contrary to Plaintiff's contention, FDA cleared the Eclipse subject to both MDA's general controls provisions, and the special controls found in 21 C.F.R. § 870.3375, including FDA's Filter Guidance.

<sup>35</sup> (Ex. 41, June 18, 2010 Letter from FDA; Ex. 42, June 21, 2010 Letter from Bard to FDA.)

<sup>36</sup> (Ex. 43, June 22, 2010 FDA Clearance.)

(citations omitted) (“[E]vidence of Bard’s compliance with FDA regulations and the FDA’s clearance of the G2 line of filters, while not dispositive, is relevant to the claims Mr. Keen brings under Pennsylvania law.”); *Lance*, 85 A.3d at 456 (“Pennsylvania courts permit[] defendants to adduce evidence of compliance with governmental regulation in their efforts to demonstrate due care (when conduct is in issue).”); *Birt v. Firstenergy Corp.*, 891 A.2d 1281, 1290 (Pa. Super. 2006) (“[E]vidence of industry standards and regulations is generally relevant and admissible on the issue of negligence.”).<sup>37</sup>

Additionally, this evidence is probative of whether the Eclipse was “too dangerous to be used by anyone” given the risks and benefits of the device and the likelihood and severity of risks of harm. As noted above, FDA down-classified IVC filters from Class III to Class II devices after “extensive review” of the “publicly available, valid scientific evidence,” and information provided by manufacturers concerning the risks and benefits of IVC filter use. (Ex. 12 at 3 (internal p. 67).) After weighing the benefits against risks, FDA concluded “that the use of [IVC filters for certain indications] does not present a potential unreasonable risk of illness and injury, and that special controls *would provide reasonable assurance of the safety and effectiveness of the device.*” (*Id.* at 3-4 (emphasis added) (internal pp. 67-68).) Therefore, the exchange of information between Bard and FDA during the regulatory review of Bard’s filters, Bard’s compliance with the regulatory process that FDA deemed adequate “*to reasonably assure that the device is safe and effective for its intended use,*” (*id.* at 8 (emphasis added) (internal p. 72)), and FDA’s clearance

<sup>37</sup> Plaintiff’s attempts to graft a “safety” limitation onto this rule are not supported by any controlling authority from the Pennsylvania Supreme Court and should be rejected. *See Keen*, 480 F. Supp. 3d at 650 n.4 (“To the extent Mr. Keen suggests that the jury is only to consider compliance evidence and regulations related to ‘safety,’ the Court rejects such a proposition.”).

of the Eclipse, is relevant evidence that the filter is not “too dangerous to be used by anyone.”

For these reasons, the MDL and *Keen* court’s analyses apply to this case. Just as the MDL Court found under Georgia law and the *Keen* court found under Pennsylvania law, evidence of Bard’s compliance with FDA regulations, and the FDA’s decision to clear the G2 line of filters, is relevant. *In re Bard IVC Filters*, 289 F. Supp. 3d at 1047-48; *Keen*, 480 F. Supp. 3d at 650-51; *see also In re Cook Med., Inc., IVC Filters Mktg., Sales Practices & Prod. Liab. Litig.*, 114ML02570RLYTAB, 2018 WL 6617375, at \*1 (S.D. Ind. Dec. 18, 2018) (denying motion to exclude evidence of IVC filter’s 510(k) clearance)<sup>38</sup>; *Block v. Woo Young Medical Co. Ltd.*, 937 F. Supp. 2d 1028, 1047 (D. Minn. 2013) (evidence of “FDA’s general expectations” of 510(k)-cleared device admissible); *Pritchett v. I-Flow Corp.*, 2012 WL 1340384, at \* 5 (D. Colo. Apr. 18, 2012) (same); *Musgrave v. Breg, Inc.*, 2011 WL 4620767, at \*3 (S.D. Ohio Oct. 3, 2011) (same).

Although Plaintiff cites decisions by Judge Goodwin in West Virginia and by Circuit Courts involving an entirely different Bard product line (surgical mesh), as well as other cases, none of those cases involved the kind of extensive regulatory history associated with Bard’s IVC filters. Moreover, those cases were merely affirmed under the highly deferential abuse of discretion standard. *See, e.g., Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1018 (7th Cir. 2020) (exclusion of FDA evidence under Rule 403 “was not an abuse of discretion” given the limited regulatory record for the product at issue). Further, the reasoning in those opinions is contrary to that of many other courts, as discussed herein. One court recently rejected the reasoning in these opinions and

---

<sup>38</sup> As Plaintiff’s counsel knows from its leadership role in the *Cook* MDL, Judge Young denied their similar motion to exclude FDA 510(k) review evidence. Plaintiff fails to cite this relevant decision, and instead misleadingly implies that courts “hearing IVC filter cases” have excluded this evidence citing to an earlier unpublished order from the *Cook* litigation. (Doc. 120 at 41.)

adopted Judge Campbell’s approach deeming 510(k) evidence admissible. *See Hrymoc v. Ethicon, Inc.*, No. A-1083-18, 2021 WL 787039, at \*1 (N.J. Super. Ct. App. Div. Mar. 2, 2021) (vacating \$83 million mesh verdicts, finding exclusion of 510(k) evidence was not fair or appropriate and “was unfairly and repeatedly capitalized upon by plaintiff’s counsel at both trials”).

**C. FDA’s clearance of the Filter is relevant because safety and efficacy play an important role in 510(k) review.**

Plaintiff erroneously asserts that just because a 510(k) clearance is not a definitive finding by FDA that a device is safe and effective it is irrelevant under any state law to the question of whether Bard’s IVC filters are safe, effective, and “not defective.” (Doc. 120 at 44.) Plaintiff’s underlying premise is false. *See Keen*, 480 F. Supp. 3d at 650 (rejecting same argument in a Bard IVC filter case). Safety and efficacy play an important role in FDA’s decision-making in the 510(k) process. Judge Campbell agreed, stating that the “SMDA did introduce safety and effectiveness considerations into 510(k) review,” even if the standard is comparative. *In re Bard IVC Filters*, 2017 WL 5625547, at \*7. This is further evidenced by FDA’s down-classification of IVC filters,<sup>39</sup> as well as the history of FDA’s 510(k) clearance of the Filter in the record—as illustrated by FDA’s own internal review memoranda—which shows that FDA reviewed the safety and efficacy of the products before clearing them.

**D. *Lohr* addressed preemption – not evidentiary standards.**

Plaintiff’s heavy reliance on *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), is misplaced. *Lohr* involved the question of whether FDA’s clearance of a 510(k) device preempts state law product liability claims under 21 U.S.C. §360k(a). *See In re Bard IVC Filters*, 2017 WL 5625547,

<sup>39</sup> (*See* Section 18.A., *supra*.)

at \*5. The *Lohr* decision did not address whether evidence of FDA’s 510(k) clearance of a device is admissible or relevant to whether a product is defective. Judge Campbell agreed, holding that, while plaintiffs (citing *Lohr*) correctly noted “that the 510(k) process focuses on device equivalence, not device safety[,] this does not render evidence of the 510(k) process irrelevant to the reasonableness of Bard’s conduct.” *In re Bard IVC Filters*, 289 F. Supp. 3d at 1047-48; *accord Keen*, 480 F. Supp. 3d at 650 (finding the plaintiff’s reliance on *Lohr* “equally meritless”).

**E. FDA’s lack of enforcement action regarding the Filter is relevant.**

Plaintiff also seeks to exclude reference to FDA’s lack of enforcement action regarding the Filter. Plaintiff’s position is erroneous for three reasons:

*First*, Plaintiff argues that Bard should have withdrawn its IVC filters from the market. Evidence that “FDA did not bring an enforcement action against Bard for its products during the nearly five years that the G2 line of filters was on the market before” Plaintiff received his Eclipse, is “relevant to whether it was reasonable for Bard to design and manufacture the [Filter] and to continue [to market it] in 2010.” *Keen*, 480 F. Supp. 3d at 651 (applying Pennsylvania law).

*Second*, based on its experience during the bellwether trials in the MDL, Bard anticipates that Plaintiff will make many FDA-related arguments at trial:

that the Recovery filter was adulterated and misbranded in violation of federal regulations, that the device should have been recalled, and that it was not substantially equivalent to its predicate device. [H]e will seek to introduce an FDA warning letter and argue that Defendants’ mishandling of complaints, including for the Eclipse filter, violated federal regulations and reflects a conscious indifference to patient safety. [H]e also will assert that Defendants misled the FDA and failed to disclose relevant information.

(Ex. 44, *In re Bard IVC Filters*, MD-15-02641-DGC, Doc. 11011 at 4 (D. Ariz. May 7, 2018).)

“To counter this evidence and argument regarding the FDA, Defendants should be permitted to

present evidence regarding their communications with the FDA and its lack of enforcement action with respect to their filters.” (*Id.* at 4); *In re Bard IVC Filters*, 2018 WL 4279833, at \*1 (applying Wisconsin law) (“[E]vidence regarding Bard’s post-market communications with the FDA and the agency’s lack of enforcement action with respect to Bard filters are relevant to Plaintiffs’ claim that Bard failed to disclose relevant evidence to and misled the FDA”).<sup>40</sup>

**Third**, given FDA’s broad authority to investigate violations of the FDCA, FDA’s decision not to take any enforcement actions against Bard, even after its post-market review, is probative of whether Bard acted reasonably in its design and warnings for the Filter. Plaintiff “do[es] not dispute that the FDA has authority to initiate a recall and other enforcement actions against a manufacturer. [That] FDA did not do so in this case has some probative value.” (Ex. 44, at 5.)

**F. FDA’s clearance of the Filter and lack of enforcement action is not unfairly prejudicial.**

Plaintiff fails to identify any legitimate basis why he will be prejudiced by evidence of FDA clearance and lack of enforcement action. Plaintiff’s Rule 403 arguments are virtually identical to those considered and rejected by the MDL and *Keen* courts. *See In re Bard IVC Filters*, 289 F. Supp. 3d at 1048-49 (the plaintiff’s concerns “can be adequately addressed without excluding relevant evidence to the detriment of Defendants.”); *accord Keen*, 480 F. Supp. 3d at 651. Plaintiff “certainly will be free to present evidence and argument that the 510(k) process is a comparative one that requires only substantial equivalence to a predicate device.” *In re Bard IVC*

<sup>40</sup> Although Judge Campbell initially reserved his ruling on this issue for the first bellwether trial, he ultimately admitted this evidence at trial overruling the plaintiff’s Rule 402, 403, 602, and 802 objections. *See In re Bard IVC Filters*, 289 F. Supp. 3d at 1050; (Ex. 2, *Booker* Trial Tr. at 1654:25 to 1655:1; 1680:1 to 1681:12).

*Filters*, 289 F. Supp. 3d at 1049.<sup>41</sup> But “[m]any of the relevant facts in this case occurred in the context of FDA 510(k) review, and much of the evidence is best understood in that context.” *Id.* “Attempting to remove any references to the FDA from the trial would risk creating a misleading, incomplete, and confusing picture for the jury.” *Id.* The jury expects to hear this evidence in a case involving a prescription medical device, and both sides have experts who can explain the FDA evidence. This expectation is “even more prevalent for cases . . . tried [during] the current COVID-19 pandemic and the FDA’s widely publicized involvement in approving COVID-19 vaccines and reviewing testing data from clinical studies.” *Hrymoc*, 2021 WL 787039, at \*15 n.18.

Moreover, it is unclear “that all FDA-references could [even] be removed, given that much of the evidence . . . comes from the FDA.” *In re Bard IVC Filters*, 289 F. Supp. 3d at 1049. “[I]f the evidence was half-baked, containing some references to the FDA but not explaining what role the FDA played with respect to the Bard filters, the jury would be left to speculate about the FDA’s involvement and conclusions.” *Id.* This is a real concern in this case, and Bard will be extremely prejudiced “if it is not permitted an opportunity to present to the jury a full picture concerning its decisions to market the G2 line of filters in 2005, and to continue marketing it through June 2010,” when Mr. Peterson received his Eclipse. *Keen*, 480 F. Supp. 3d at 651. “During this time period, Bard was in frequent communication with the FDA regarding the performance of the G2 line of filters, Bard was performing a clinical trial on the G2 filter (at the FDA’s request), and the FDA

---

<sup>41</sup> Plaintiff’s concern that he will be prejudiced because of the risk of confusion as to whether Bard filters were found by FDA to be safe and effective can be alleviated, “*if necessary*, by a limiting instruction regarding the nature of the 510(k) process,” as Judge Campbell recognized. *In re Bard IVC Filters*, 289 F. Supp. 3d at 1049 (emphasis added). He ultimately ruled that the limiting instruction was not necessary at the bellwether trials because the presentation of the evidence did not present any risk of jury confusion. (*See, e.g.*, Ex. 12, *Booker* Trial Tr. at 2447:18-19.)

cleared Bard's G2 line of filters [eight] times." *Id.* Removing this evidence creates an uneven playing field, leaving the jury with an incomplete picture concerning this design history.

Further, the prejudice that Plaintiff seeks to impose on Bard is amplified by the evidence that Bard anticipates Plaintiff will seek to present at trial: that Bard allegedly violated FDA regulations and/or federal law, and that Bard defectively designed the G2 line of filters by failing to implement design improvements from its later-generation filters. In other words, Plaintiff would ask this Court to issue an order allowing him to present evidence to the jury that the Filter violates FDA's regulations based on comparisons to the SNF (Bard's permanent-only filter), and that Bard did not make design improvements from its later-generation filters, yet precluding Bard from presenting evidence regarding the steps it took to demonstrate to FDA that the filters should be legally marketed, FDA's multiple clearances of the devices, as well as the extensive design, testing, and regulatory clearance processes required before any design changes could be implemented. The true prejudice comes from excluding this evidence, as it is undeniable that the Eclipse, like every other prescription medical device, could not be marketed without prior FDA review. Without this evidence, the jury will be left to speculate about what happened.

**G. FDA's clearance and lack of enforcement action will not result in a mini-trial.**

Plaintiff argues that allowing FDA evidence will result in a mini-trial on 510(k) review and whether Bard complied with FDA regulations. But as evidenced by all three bellwether trials in the MDL that were tried within strict time limits, these cases can and have been tried without unnecessary delay. Judge Campbell was correctly "convinced that efficient management of the evidence and adherence to the Court's time limits will avoid any risk of unnecessary or time-consuming mini-trials." *In re Bard IVC Filters*, 289 F. Supp. 3d at 1049; *accord Keen*, 480 F.

Supp. 3d at 651. Nor have these perceived concerns been borne out in the innumerable previous trials involving all sorts of prescription drug and devices, including 510(k) cleared devices, that have occurred in various jurisdictions. Rather, evidence regarding the 510(k) process and Bard's compliance with FDA regulations is an important part of the entire story in this case.

**19. Any reference to IVC filters as lifesaving devices or to statistics of thrombi and pulmonary emboli.**

IVC filters are lifesaving devices and have a clear benefit: Bard's experts have so opined; Plaintiff's experts have so opined; Plaintiff's own doctor has so opined; and medical literature provides support for this proposition. Thus, Plaintiff's argument that there is "absolutely no evidence whatsoever" showing that IVC filters can save lives or that IVC filters do not have "any form of clinical benefit" is without merit. (Doc. 120 at 51, 56.)

This evidence is relevant to Plaintiff's design and failure to warn claims and is not unduly prejudicial. "Evidence is not irrelevant and unduly prejudicial merely because it conflicts with one party's side of the story." *Keen*, 480 F. Supp. 3d at 652. There is no legal basis for Plaintiff to prevent Bard from presenting evidence to the jury related to the clinical benefits of its IVC filters. Plaintiff is free to use the evidence cited in his motion (assuming it is admissible) to cross-examine Bard's witnesses. Furthermore, this precise evidentiary issue was litigated in the MDL where Judge Campbell ruled against the MDL plaintiffs on their similar motion *in limine* and ordered that Bard could present evidence that Bard's IVC filters are lifesaving medical devices. Most recently, the *Keen* court also rejected the arguments presented in this motion and ordered that Bard can introduce evidence relating to the clinical benefit of IVC filters and the devices' ability to save lives because such evidence is admissible and relevant and under Pennsylvania law. This Court should do the same.

**A. There is abundant evidence showing that Bard's IVC Filters can be lifesaving.**

Plaintiff's argument is premised on a false claim that "[t]here is absolutely no evidence whatsoever to suggest that any of Bard's IVC Filters are indeed 'lifesaving' devices or even offer any form of clinical benefit." (Doc. 120 at 51.) Both parties' retained experts, as well as Plaintiff's implanting physician, have provided evidence that filters can be lifesaving medical devices and that the devices' clinical benefit is to prevent potentially deadly PE. Additionally, medical literature supports the notion that filters can be lifesaving devices and have a clinical benefit.

Bard's Interventional Radiology expert witness, Dr. Clement Grassi, explains that IVC filters "provide mechanical 'trapping' against the threat of pulmonary embolus (PE)." (*See* Dr. Clement J. Grassi, MD, FSIR Rule 26 Rep. at 3 (Doc. 101-12).) Dr. Grassi opines that pulmonary embolism is a major cause of death in the United States with up to 200,000 deaths each year caused by PE. (*Id.* at 2.)<sup>42</sup> Once the filter is deployed, these devices act as "filters or 'sieves' to stop the passage of large clots to the heart and lungs." (*Id.* at 3.) "After capture by the filter such thrombi (clots) are lysed (dissolved naturally) by the body's bloodstream, rather than traveling suddenly to the lungs, and causing a catastrophic event (e.g. major pulmonary embolism)." (*Id.*) Dr. Grassi further states that "[a] consensus exists among groups of physicians who place filters that they are a valuable and potentially life-saving devices." (*Id.* at 10.)

Plaintiff's implanting physician, Dr. Goodman, testified that he believes IVC filters are "a valuable tool that we have in medicine to help protect patients from pulmonary embolism," which

---

<sup>42</sup> (*See also* Ex. 45, ACR-SIR-SPR *Practice Parameter for the Performance of Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism*, at 2 ("Pulmonary embolism (PE) continues to be a major cause of morbidity and mortality in the United States. Estimates of the incidence of nonfatal PE range from 400,000 to 630,000 cases per year, and 50,000 to 200,000 fatalities per year are directly attributable to PE").)

he states “is in the top ten causes of death in the United States.” (Ex. 8, Dr. Goodman Dep. at 35:1-16, 50:5-51:6.) Dr. Goodman went on to provide direct evidence that IVC filters can be lifesaving devices — testifying “I generally believe filters protect people from death.” (*Id.* at 64:9-65:15.)

Plaintiff’s experts likewise have opined that IVC filters can be lifesaving devices because they protect against the potentially deadly medical event of a PE. Dr. Thomas Kinney testified that PE causes as many as 240,000 deaths each year in the United States and that doctors use IVC filters to “prevent the pulmonary embolism” when patients are either unable to take anticoagulant medication or still at risk of forming a clot despite the medication. (*See* Ex. 46, June 17, 2017 Dr. Thomas Kinney Dep. at 109:7-112:17.) Dr. Kinney further stated that because IVC filters prevent deadly PE, the devices are “viewed as potentially lifesaving medical devices.” (*See id.*) Presumably because of these benefits, Dr. Kinney went on to confirm that he still implants IVC filters in his patients. (*See id.*) Similarly, Dr. Michael Streiff, Plaintiff’s hematology expert, testified that IVC filters have benefits and can be lifesaving devices. (*See* Ex. 47, July 12, 2017 Dr. Michael Streiff Dep. at 115:14-22.)

Finally, the medical literature supports Bard’s argument that IVC filters can be lifesaving and have a clinical benefit. For example, *Prophylactic and Therapeutic Inferior Vena Cava Filters to Prevent Pulmonary Embolism in Trauma Patients* found that prophylactic use of an IVC filter in trauma patients reduced mortality from 11% to 3%, and that none of the patients who received a prophylactic IVC filter experienced a PE. (*See* Ex. 48, Carlin, *Prophylactic and Therapeutic Inferior Vena Cava Filters to Prevent Pulmonary Emboli in Trauma Patients*, 137 *Archives of Surgery* 521, 521 (2002); *see also* Ex. 49, DeYoung, *Inferior Vena Cava Filters: Guidelines, Best Practice, and Expanding Indications*, 22 *Seminars in Interventional Radiology* 65, 68 (2016))

(discussing a meta-analysis that found “an association between IVC filter placement and lower rates of symptomatic and fatal PE in the trauma patient population”).) This is just some of the medical literature that Bard’s witnesses will use to show the jury that IVC filters can be lifesaving devices.

**B. Evidence that Bard’s Eclipse Filter has a clinical benefit and can be a “lifesaving” device and statistics related to pulmonary emboli are relevant.**

The lifesaving nature of the Eclipse Filter is relevant to the Parties’ claims and defenses generally and to provide the jury with the necessary context about the nature of the product. Without understanding the risks and benefits of the filter at issue, the jury would be left without the proper context to understand why Bard would ever design or manufacture IVC filters and why Dr. Goodman would ever use the Eclipse with Plaintiff. Indeed, without evidence of the lifesaving characteristics of the filter, Plaintiff would be left to present evidence about complications of Bard’s filters only. Not only would Bard be unduly prejudiced in such a lopsided scenario where the jury hears only negative evidence about its filter, but this scenario would be completely divorced from the way that doctors treat patients in the real world with IVC filters, and from the way that Dr. Goodman treated Plaintiff in this case with the Eclipse.

Moreover, evidence that Bard’s IVC filters have a clinical benefit and can be lifesaving devices is relevant and probative to Plaintiff’s negligent design claim. Bard designed its IVC filters to perform one function: to capture blood clots before they become potentially life-threatening PE. (*See* Doc. 96 at 3.) Thus, evidence related to the sole design-purpose of the Eclipse is highly probative to the jury’s consideration of whether Bard was negligent in the design process. Additionally, statistics regarding the frequency of PE in the United States each year are also

probative to provide the jury with a complete picture of the Eclipse's use and function—preventing a medical event that causes up to 200,000 deaths each year in this country. (*See* footnote 41, *supra*.)

Additionally, evidence of the potential lifesaving benefit of the Eclipse is relevant to rebut Plaintiff's failure to warn claim. It appears from this Motion that Plaintiff intends to present evidence to the jury that Bard knew the Eclipse offers no clinical benefit to patients, that the Filter was not a lifesaving device, and that Bard allegedly failed to warn of the same. Bard intends to present evidence relating to the Eclipse's ability to prevent blood clots from reaching a patient's heart or lungs to rebut these claims.

Finally, Plaintiff's "absence of evidence is evidence of absence" argument is inaccurate. Plaintiff cites to the deposition testimony of a former Bard marketing employee (Ms. Hudnall) to argue that there is no evidence IVC filters have a clinical benefit. (Doc. 120 at 53-54.) Aside from the fact that Ms. Hudnall is not a doctor qualified to offer a reliable opinion on the issue (as opposed to the experts cited above who are so qualified), Ms. Hudnall's referenced testimony merely states, accurately, that it is not possible to determine the exact number of clots that Bard's filters have "caught" over time and stopped from entering the heart or lungs. (*See id.*) She explains that this is because patients with Bard's IVC filters implanted could be living life unaware that their filter contains a clot burden which, absent the filter, may have led to a deadly PE. (*Id.*) The impossibility of documenting every event when Bard's IVC filters prevented a PE should not preclude Bard from offering relevant evidence, through witnesses who have the foundation to testify, that the purpose of these filters is to prevent a potentially fatal event. Nor should it preclude statistics showing how many people experience a PE each year.

Furthermore, the testimony cited by Plaintiff from Bard's expert, Dr. Hennebry, fails to establish that there is no evidence Bard's filters can be lifesaving devices. (*Cf.* Doc. 120 at 54.) Rather, Dr. Hennebry testified that, while there are no randomized controlled clinical trials relating to IVC filter use, there is evidence that filters "catch clots," and therefore have efficacy in protecting potentially life-threatening pulmonary embolism. (*Id.*)

**C. Judge Campbell in Bard's IVC Filter MDL denied a similar motion *in limine* trying to exclude evidence that filters are lifesaving devices, and recently the Eastern District of Pennsylvania (applying Pennsylvania law) did the same.**

The MDL plaintiffs in the first bellwether trial filed a motion *in limine* to exclude descriptions of IVC filters as lifesaving or life-extending devices. Judge Campbell denied the motion for the same reasons Bard argues that Plaintiff's motion should be denied here. *See In re Bard IVC Filters*, 2018 WL 1109554, at \*\*4-5. Judge Campbell first noted that the MDL plaintiffs agree (as does Plaintiff here), that IVC filters are designed to prevent blood from reaching the heart and lungs. *See id.*; (Doc. 120 at 50.) He then found that preventing blood clots from reaching the heart and lungs "saves lives" because hundreds of thousands of people die from PEs each year. *In re Bard IVC Filters*, 2018 WL 1109554, at \*5. Accordingly, the MDL court found that there is evidence, including some from Plaintiff's expert Dr. Kinney, that Bard's IVC filters are lifesaving devices and that such evidence is "directly relevant" to the MDL plaintiff's design defect claims. *Id.*

More recently, the *Keen* court also denied a motion seeking to exclude the same evidence Plaintiff tries to prevent Bard from presenting in this case. *See Keen*, 480 F. Supp. 3d at 652-53. Judge Pratter ruled that this evidence was admissible and relevant to the plaintiff's design

allegations under Pennsylvania law, which also applies in this case. For the reasons expressed by the MDL and *Keen* courts, Plaintiff's motion *in limine* should also be denied.

**D. The medical literature cited by Plaintiff does not show that Bard's IVC Filters have no clinical benefit or that they are not lifesaving devices.**

Contrary to Plaintiff's suggestions, medical literature related to the use of IVC filters does not establish that Bard's IVC filters cannot be lifesaving devices or that IVC filters have no clinical benefit. For example, Plaintiff relies on a 2019 article in the New England Journal of Medicine, entitled, *A Multicenter Trial of Vena Cava Filters in Severely Injured Patients* to argue that IVC filters have no efficacy. (*See* Doc. 120 at 56-57.) But the article specifically concludes otherwise: Patients who had intracranial hematomas or contusions and who cannot take anticoagulants because of the risk of bleeding "may benefit from the use of a vena cava filter as a temporizing measure to prevent symptomatic pulmonary embolism." (Doc. 120-47 at 9.) The other studies cited in Plaintiff's Motion are equally unpersuasive.

**E. Relevant evidence related to the purpose of Bard's IVC Filters should not be excluded pursuant to Rule 403.**

Although Plaintiff argues that evidence about the Eclipse Filter's benefits should be excluded pursuant to Rule 403, he does not identify how this evidence presents any risk of unfair prejudice towards him, confusing the issues, misleading the jury, or needlessly presenting cumulative evidence, let alone how those risks *substantially* outweigh the evidence's probative value. As such, Plaintiff's argument fails.

**CONCLUSION**

For the foregoing reasons, the Court should deny Plaintiff's Motion.

Dated: April 16, 2021.

GORDON REES SCULLY MANSUKHANI, LLP

By: s/ Nancy M. Erfle

Nancy M. Erfle, OSB No. 902570

[nerfle@grsm.com](mailto:nerfle@grsm.com)

GORDON REES SCULLY MANSUKHANI, LLP

1300 SW Fifth Avenue, Suite 2000

Portland, OR 97201

Telephone: (503) 382-3852

Facsimile: (503) 616-3600

Taylor T. Daly (admitted *pro hac vice*)

[Taylor.daly@nelsonmullins.com](mailto:Taylor.daly@nelsonmullins.com)

Brandee J. Kowalzyk (admitted *pro hac vice*)

[Brandee.kowalzyk@nelsonmullins.com](mailto:Brandee.kowalzyk@nelsonmullins.com)

Richard B. North, Jr. (admitted *pro hac vice*)

[Richard.north@nelsonmullins.com](mailto:Richard.north@nelsonmullins.com)

Shaniqua L. Singleton (admitted *pro hac vice*)

[Shaniqua.singleton@nelsonmullins.com](mailto:Shaniqua.singleton@nelsonmullins.com)

Philip M. Busman (admitted *Pro Hac Vice*)

[Phil.busman@nelsonmullins.com](mailto:Phil.busman@nelsonmullins.com)

James F. Rogers (admitted *pro hac vice*)

[jim.rogers@nelsonmullins.com](mailto:jim.rogers@nelsonmullins.com)

Elizabeth C. Helm (admitted *pro hac vice*)

[kate.helm@nelsonmullins.com](mailto:kate.helm@nelsonmullins.com)

Mark R. Nash, admitted *Pro Hac Vice*

[Mark.nash@nelsonmullins.com](mailto:Mark.nash@nelsonmullins.com)

NELSON MULLINS RILEY & SCARBOROUGH LLP

201 17th Street NW, Suite 1700

Atlanta, GA 30363

*Attorneys for Defendants C.R. Bard,  
Inc. and Bard Peripheral Vascular, Inc.*

**CERTIFICATE OF COMPLIANCE**

I hereby certify that this memorandum complies with this Court's March 16, 2021 Order granting the Parties' request for a 50-page limit for Motions *in Limine* because it does not exceed 50 pages, including headings, footnotes, and quotations, but excluding the caption, table of contents, table of cases and authorities, signature block, exhibit, and any certificates of counsel pursuant to Local Rule 7-2(b).

Dated: April 16, 2021

GORDON REES SCULLY MANSUKHANI, LLP

By: s/ Nancy M. Erfle

Nancy M. Erfle, OSB No. 902570

[nerfle@grsm.com](mailto:nerfle@grsm.com)

**CERTIFICATE OF SERVICE**

I hereby certify that I caused a true and correct copy of this document to be filed on the 16th day of April, 2021, via the CM/ECF filing system which will transmit a service copy of the same to all counsel of record.

Dated: April 16, 2021.

GORDON REES SCULLY MANSUKHANI, LLP

By: s/ Nancy M. Erfle

Nancy M. Erfle, OSB No. 902570

[nerfle@grsm.com](mailto:nerfle@grsm.com)